Exhibit D

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION - ATLANTIC COUNTY
Civil Action Case No. 291 CT
Honorable Carol E. Higbee, P.J. Cv.

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IN RE: :
PELVIC MESH/GYNECARE :
LITIGATION : Master Case No.
: L-6341-10
(GENERAL, GROSS, WICKER) :

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CONFIDENTIAL - ATTORNEYS' EYES ONLY

Videotaped Deposition of TIMOTHY A. ULATOWSKI, M.S.

Washington, DC

Thursday, November 29, 2012

9:36 a.m.

VOLUME 1

Reported by: Debra A. Whitehead

Videotaped Deposition of TIMOTHY A. ULATOWSKI, M.S., held at the offices of:

O'MELVENY & MYERS, LLP
1625 Eye Street, NW
10th Floor
Washington, DC 20006
(202) 383-5300

Pursuant to Notice, before Debra A. Whitehead, an Approved Reporter of the United States District Court and Notary Public.

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ALSO PRESENT:
Michael Gay, Videographer

C O N T E N T S

E X H I B I T S
(Attached to the Transcript)

EXHIBITS CONTINUED

EXHIBITS CONTINUED

Reserved for Confidential Designation Index as Pursuant to the Protective Order

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P R O C E E D I N G S

(Ulatowski Exhibits 1 through 5 marked for identification, to be attached to the transcript.)

VIDEO SPECIALIST: We are on the record. The time now is 9:36.

This marks the beginning of Disk Number 1 for the videotaped deposition testimony of Tim Ulatowski in the matter of In Re Pelvic Mesh Litigation. This case is pending in the Superior Court of New Jersey, Law Division, Atlantic County, Civil Action Number 291 CT.

Today's date is November the 29th, 2012. This deposition is being conducted at 1625 Eye Street, Northwest, Washington, D.C.

Will all attorneys present please identify themselves and who they represent.

MR. MAZIE: David Mazie; Mazie, Slater, Katz & Freeman, on behalf of plaintiff.

MR. GRAND: Jeff Grand; Bernstein, Liebhard, on behalf of plaintiffs.

MR. STUART: William Stuart; Sills, Cummis & Gross, on behalf of Caldera Medical.

MS. KABBASH: Maha Kabbash from Riker, Danzig, on behalf of defendants J&J and Ethicon.

MR. GAGE: William Gage; Butler, Snow;

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defendants J&J and Ethicon.

VIDEO SPECIALIST: My name is Michael Gay, I am with Golkow Technologies. Our court reporter today is Debbie Whitehead, also with Golkow Technologies, who will now swear in our witness.

TIMOTHY A. ULATOWSKI, M.S.,

having been duly sworn, testified as follows:

VIDEO SPECIALIST: You may proceed.

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MR. MAZIE:

Q Mr. Ulatowski, my name is David Mazie, and I represent the plaintiff in a case in which you've been named as an expert witness.

How many times have you been deposed before?

A It's six times now.

Q Okay. And when was the first time you were ever deposed?

A The first one may have been -- as far as date is concerned?

Q Yeah.

A Probably the fall of -- of last year.

Q Okay. Can you give me the names of the cases in which you were deposed and who you were testifying on behalf of, what party?

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A Yeah, let me turn to my report, which has a listing.

Okay first --

Q Why don't we step back. Is it listed in your report?

A Yes, it is.

Q Okay. What page?

A Page 74. One is not listed because it just occurred last week.

Q So -- why don't we do this. I have marked as -- we'll do it this way.

Ulatowski 1 is your CV. Is that your current CV?

A Let me examine it.

Not quite.

Q Okay. What's missing from that CV?

A Well, my current title at Becker & Associates Consulting has changed. I've become an employee of Becker & Associates Consulting.

Q And what is the --

A And my current title is director of the medical device practice at Becker & Associates Consulting.

Q Anything else on your CV that I have marked as Ulatowski 1 that's inaccurate?

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A That's probably -- that's probably it.

Q When did you become an employee?

A July-ish.

Q Okay.

A July this year.

Q Let me show you Ulatowski 2. This is your main report in this case?

A Yes. Uh-huh.

Q Okay. On the last page there's a listing of depositions where you've been deposed?

A Yes.

Q Okay. And you said there was one additional deposition you've given?

A Yes.

Q What case was that in?

A It was -- it was a product liability case. I testified for a defendant. ASR, hip, for DePuy.

Q Okay. And you were an expert on behalf of DePuy?

A Yes.

Q Okay. Where is that case pending?

A Yes.

Q Where is that case pending?

A Oh, where is that case pending.

In the -- in the midwest. I don't recall

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exactly the state. I'll have to check my records.
Q Okay. And this is a complete list, then, these five plus that one occasion are the six times you've been deposed?
A That's correct.
Q Okay. Have you ever testified in a civil litigation? And I mean in court.
A In court? No, I haven't testified in court in a civil litigation.
Q Okay. Have you ever testified in court in a criminal litigation?
A Yes.
Q Okay. On how many occasions?
A Once.
Q When was that?
A As an employee of the Food and Drug Administration, I testified for the government in that case. It was a case in Chicago, district court, federal court. It was a criminal case. The company was Abtox. The litigants on the other side, Ross Caputo was one name.
Q Okay. What was the issue in that case?
A Well, the criminal charges were -- were various. I know the postal service was part of the case, another agency, maybe SEC, was part of the case.

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And as well as FDA.
There were -- there were many different aspects of -- of the case, so -- wire fraud and things like that.
Q You also issued a supplemental report, which I've marked as Ulatowski 3. Is that correct?
A Yes, that's correct.
Q Is that your only supplemental report in this case?
A Yes.
Q Is it fair to say that your initial report which is Ulatowski 2, and your supplemental report which is Ulatowski 3 contain all of your opinions in this case?
A Yes.
Q Okay. Ulatowski 4 is an Appendix B, or an updated Appendix B, we received the other day. Is that the most current Appendix B?
A And this was received by -- from, rather, from counsel?
Q Yes.
A Well, I'd have to compare line by line, but I assume that to be the case.
Q Okay. Does Appendix B list all the materials and references that you've reviewed or

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relied on in this -- in arriving at your opinions in this case?
A If it's the same list that's in my report, the answer would be yes.
Q Okay.
MR. MAZIE: Well, I'll ask counsel. You gave us a revised Appendix B I think about two days ago. That's the one that I have marked. Is that the most current?
MS. KABBASH: Yes, my understanding is that is the most current. We have not served -- we have not attempted to serve on you anything more recently than that.
MR. MAZIE: Okay.
BY MR. MAZIE:
Q So the Appendix B that is before you that was served on us two days ago, does that contain all the materials and sources that you've reviewed or relied on in arriving at your opinions in this case?
A I believe that would be the case, if -- it accurately represents all the material provided. I'd have to compare what I have in my original report against this just to be sure what -- what was added.
I did receive additional material after this report in terms of the supplemental.

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Q Well, do whatever you need to do. All I want to make sure is that that contains all the information you reviewed or relied on in arriving at your opinions in this case.
A I would believe that to be the case.
Q Okay. I'm just going to give you a couple of ground rules of the deposition. First of all, do you understand that you're under oath?
A Yes.
Q You understand that your testimony has the same force and effect as if you were sitting before a judge and a jury in a courtroom at this time?
A I do.
Q If you answer a question, I'm going to presume you understood that question. If you don't understand the question or any portion of the question, let me know, and I'll rephrase it. But if you answer it, I'll presume you understand it. Okay?
A Understood.
Q Okay. We don't want you to speculate. We don't want you to guess. If you remember something or you know something, you let us know that. But please don't speculate or guess. Okay?
A Okay.
Q We received a few days ago what's been

marked as Ulatowski 5, which is the ICMJE form for disclosure of potential conflicts of interest, as one of the documents that you reviewed. I'm going to show that to you.

Is that something that you reviewed in arriving at your opinions in this case?

A Let me examine it.

Yes, I recall seeing this.

Q Okay. Why did you review this document?

A I was -- received it, and I examined it in relation to a particular journal article that's part of -- referenced in my reports. I think that was a connection.

Q Okay. And you're talking about the Altman article?

A Yes.

Q Okay. What was particularly relevant about the ICMJE form?

A Well, any interest in regard to allegations regarding bias or interactions between Altman and others. And then I wanted to see what sorts of agreements there were, related documents regarding that, that particular type of issue.

Q Did you arrive at any conclusions concerning this ICMJE disclosure form concerning

potential conflicts of interest?

A Well, conclusions to the effect that I reviewed it, examined, see what was said, what was attested to in the documents.

Q I understand you reviewed it, and that's one thing. Did you arrive at any conclusions after reviewing this document?

A Well, I didn't express any opinions specifically in regard to this particular document --

Q Okay.

A -- if that's what you are asking.

Q All right. So this is just one -- one additional piece of information you reviewed.

A Yes.

Q And you haven't arrived at any opinions after reviewing this document, additional opinions.

A Well, I have beliefs regarding the Altman article after I reviewed the Altman article, in the general sense of issues regarding any bias that may have come up or been alleged.

Q Okay. What are those opinions or beliefs?

A Well, I think that there may have been -- or there may be an allegation that a party or parties may have had certain inputs into the Altman article, which may have biased the conclusions of the article,

the contents of the article. So I wanted to see what was disclosed, what -- what concerned that issue.

Q Okay. After reviewing this document and after being made aware of the allegations, did you arrive at any opinions concerning the propriety of those allegations, or is that something you're leaving for somebody else in this case?

A Well, I did -- if what you're getting at is did I review the Altman article, did I review inputs, comments, potential edits from others to gauge, to the extent I could, their impact on the Altman article, the final product, I did -- I did look at those things, and -- if you want to ask questions about that.

Q My question simply is did you arrive at any conclusions that you're going to express in this case concerning the allegations involving the Altman article.

A Well, from all the information I was provided and from my assessment of all that information, to the extent I could assess the information based upon my expertise, my knowledge, I didn't believe that those inputs provided by others, be it edits or comments, had any significant impact on the Altman paper.

Q Okay. Have you ever submitted an article to a journal for publication?

A Not directly.

Q Okay. Have you ever indirectly submitted an article to a journal for publication?

A Well, I've been part of publications in texts, perhaps in journals. I don't -- I've had a long career. I probably participated in some contributions to articles along the way.

Q Okay. Do you have expertise in determining when it is appropriate or inappropriate to make disclosures concerning individuals who have added input to articles being submitted to journals?

A Well, that's the reason I wanted to evaluate whatever information was pertinent to that particular issue.

MR. MAZIE: I object and move to strike as nonresponsive.

BY MR. MAZIE:

Q My question is, do you have expertise, do you claim to have expertise in the ethics rules regarding what is appropriate or inappropriate by way of disclosure of individuals involved in contributing to articles being submitted to journals for potential publication?

A Well, expertise in regard to being knowledgeable about every journal's requirements for disclosure, statements made in the articles, information provided to the editorial board, those vary from journal to journal.

I don't have specific -- specific expertise in -- in those journal procedures. That's why I wanted to see this information.

Q Okay. You're not an expert in the ethics of what should and should not be done when submitting an article to a journal, are you?

A Only in the broadest sense that certain connections, associations, should be disclosed in articles. And so I'm used to seeing that, I expect to see that. I've examined that over the course of my career.

Q Okay. And have you ever been a primary author on any article?

A Well, as I said, I've contributed to text, so I've been the primary author on chapters in textbooks --

Q Okay.

A -- for example.

Journal articles, you're testing my memory now, and I don't recall.

Q As you sit here today, you don't recall ever being the primary author on a journal article. Correct?

A I don't recall. I'm not saying that I haven't been; just I don't recall.

Q Okay. And you say that you've been the primary author on articles that have been published in textbooks?

A Yes.

Q Okay. On how many occasions, or for how many articles?

A It would be a guess. I would -- I would think two, three texts.

Q Okay. And those are in textbooks?

A Well, texts that may be otherwise characterized as -- well, texts, yes, in one instance. Proceedings of conferences, those sorts of things.

Q I'm trying to get an understanding of when you've been the primary author on -- on an article or text. How many --

MR. MAZIE: Strike that.

BY MR. MAZIE:

Q You've said that there's been three times that you've been the primary author of -- of material that's been published?

A I was -- I was guessing at two or three.

Q Okay.

A I don't recall specifically.

Q And how many of those were associated with a conference where a presentation was given?

A Well, at least one, maybe more than one.

Q Okay. Putting aside a conference, how many times have you been involved in -- as a primary or even a secondary author on materials that have been published in a magazine, a journal, a textbook, something that has been actually printed up and circulated en masse, as opposed to just in a conference?

A I -- I don't recall. It's been quite a number of years since I've done that.

Q As you sit here today, you can't give us any instances where you have been the primary or secondary author on a -- an article submitted to a journal or that's part of a textbook or any other type of publication that's been circulated en masse, aside from a conference. Correct?

A Well, I don't recall. It wasn't my style to -- in CVs, as others will do, to list every contribution, every paper, every speech, every -- every public participation. I just haven't done that

over the years.

Q You can't give us any. Correct? As you sit here today, you can't give us any examples.

A Well, I will say that during the course of my career, at particular points in my career I've been considered an expert in certain technology areas, and I've contributed to articles with others either at the FDA or the Centers for Disease Control and Prevention, Environmental Protection Agency. So I just haven't categorized that and listed those things.

Q Okay. Just so we're clear and the jury is clear, Mr. Ulatowski, as you sit here today at your deposition, you can't name one article or one chapter or one text that you were the primary or secondary author on that was published en masse, aside from participating at a conference. Correct?

A Yeah, I can't. I haven't looked at those in years and years.

Q So you can't.

A That's correct, I can't give you the journal or the date or anything of that sort.

Q Okay.

A It's not in my CV.

Q Okay. Have you ever been a peer reviewer for a medical journal?

A No.
Q Have you ever served as an editor for a medical journal?
A No.
Q Have you ever had any conversations with anyone at the New England Journal of Medicine about any topic?
A Regarding any topic?
Q Yeah.
A Perhaps.
Q As you sit here today, can you tell us when and to whom you spoke to at the New England Journal of Medicine?
A I don't recall over the course of 40 years at FDA, and participating in conferences and associations. In the New England area, Boston area, you run into many people, have conversations about many things.
Q All right.
A I don't specifically recall.
Q Have you ever spoken to any of the witnesses in this case?
A No.
Q You obviously never spoke to any of the authors of any articles, including but not limited to

Dr. Altman. Correct?
A That's correct.
Q Okay. Let's turn for a second to your CV. You currently work for how many companies?
A One.
Q Becker?
A Becker & Associates Consulting.
Q Okay.
A Who is owned by NSF International.
Q Owned by whom?
A NSF International.
Q What is NSF International?
A It's a company based in Michigan that concentrates in the healthcare area as far as testing, auditing, across many types of product lines.
Q Okay. And at some point you had another consulting company, Ulatowski Consulting?
A When I first left the government, I -- I began Ulatowski Consulting, LLC, because some clients initially approached me directly as far as particular tasks they wanted me to do. So I billed them directly, contracted with them directly, through Ulatowski Consulting, LLC.
Q And you left the government in January of 2011?

A Yes.
Q So you've been in the private sphere for almost two years?
A Almost two years.
Q Okay. And how long were you working at Ulatowski Consulting?
A Well, the entity still exists, but I haven't contracted with anyone under that -- under Ulatowski Consulting for many, many months.
Q Okay. How many clients did you have while you were at Ulatowski Consulting?
A I don't recall a specific number. I'll just speculate it's six.
Q Okay. And what type of consulting did you do at Ulatowski Consulting?
A A couple -- my -- what I do is primarily in two areas. One is -- is regulatory support for medical device and drug companies, quality systems, manufacturing, premarket tasks. The other side -- generally, just to lump them into two categories -- is -- is litigation support.
I think the first client I had was for plaintiff against a medical device company. I was on the plaintiff's side. I still am on the plaintiff's side.

Q Okay. What case is that?
A It's a -- it's a Florida employees' union against Baxter International.
Q Is that listed in your CV?
A No. I haven't been deposed.
Q What's the allegation in that litigation?
A Well, the employees union is -- is alleging that Baxter International -- I'll try and boil this down -- withheld certain information regarding some of its products, the status of interactions with FDA; and the employees' union, who had invested in Baxter, by the lack of full disclosure, suffered in the market, stock market.
Q Any issues of 510-K approval in that litigation?
A No. Well, broadly it concerns 510-Ks, but I mean, it's not -- not primarily an issue of a 510-K decision or change or something like that.
Q Okay. Is that the only plaintiff's case you've ever worked as -- on on behalf of plaintiff?
A No.
Q Okay. What other cases have you had in which you've been an expert witness in which you've been named on behalf of the plaintiff?
A I'm not sure I can disclose a couple of

them because they -- they settled, and the court -- I was under a court order as far as withholding information. In fact, I had to destroy documents after the settlement. So I will probably just -- but generally, a couple plaintiff's issues against a company.

A wrongful termination suit, I was on plaintiff's side a couple of times.

Q Mr. Ulatowski, the fact that you were an expert witness in a litigation, and the existence of litigation is not privileged. The documents that you were provided may have been designated as confidential, and some of the testimony may have been designated confidential. But certainly not the -- the existence of the litigation or the fact that you were actually named as an expert witness would not be confidential.

So all I am asking you right now is, on what cases were you named as an expert on behalf of the plaintiff, and generally what did the cases involve?

MR. GAGE: Objection to the portion of the question that -- that -- well, David, here's the deal: If he was disclosed as an expert, I agree with you. If he was publicly disclosed, but there are cases

where he might not have been disclosed as an expert, and so, therefore, his involvement would have been -- would not have been known, would have been confidential.

So I don't know. I hadn't talked to him about this specific case. But I did want to draw that distinction, because I think that -- that possibly is what he's talking about.

MR. MAZIE: Why would -- why would the fact that he was a consulting expert be precluded from discovery?

MR. GAGE: Because a lot of times you have agreements or contracts with the party that says I'm going to be retained as a consulting expert, and your identity and retention will be kept confidential unless and until counsel makes the decision to disclose you as a -- as a testifying expert.

MR. MAZIE: We don't know that, though.

MR. GAGE: But, I mean, go ahead and ask him if he knows. I'm not trying to -- I'm just trying to make sure there's a distinction there.

BY MR. MAZIE:

Q All right. First of all, on how many occasions have you been disclosed as an expert on behalf of a plaintiff in a litigation?

A I guess there's the rub. I don't know that. I don't know how far it advanced before there was settlement. And so I just -- I don't know.

Q All right. Let me ask you this: On how many occasions have you issued an expert report on behalf of a plaintiff in a litigation?

A I'll have to examine my reports I'm thinking of just to be certain about the plaintiff's identity and disclosure. Not that I'm trying to avoid the answer, but I don't want to misspeak.

Q Okay. Is that something you'll be able to do on a break or contact somebody at your office?

A No. I -- all those records I have at home.

Q Okay. Something we can deal with tomorrow?

A Perhaps, yes.

Q Well, are all the records we're talking about at your house?

A Probably, but I can't say with certainty.

Q Okay. Is there someone at your office -- if they're at your office, is there someone at your office that can help you get copies of what you need?

A I will -- I'll explore that during a break.

Q What I'm going to ask you to do is to produce to us -- at a minimum identify, but certainly have copies so we can at least have them marked, and

if somehow it's confidential -- you deem it confidential, you'll give that to counsel, defense counsel, and he'll take that. And then if we have to, we'll fight over it later on.

But I do need you to bring with you tomorrow morning any depositions and expert reports in any case in which you were an expert, whether it be the plaintiff or the defense.

A I want to be clear on this. You want all my reports?

Q I want all your reports. I want all your depositions in any case. You've only been doing this for about two years.

A Yeah, I understand that.

Q There shouldn't be too many.

But, yes, that's what I want.

And then if there's an issue as to any of them, you'll give that to counsel, and we'll deal with it ourselves. But at a minimum, we need you to produce those to at least counsel, and then he'll give me what he thinks is appropriate. And if there are any that we need to fight over, we'll fight over. But at least he'll have possession of it.

A I understand. I -- I just -- you know, after signing court orders about disclosures and

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whatnot, I'm a little cautious about these things.
MR. GAGE: Well, we'll -- we'll work off this.
BY MR. MAZIE:
Q Yeah, I just -- I just need you to bring it. And you're not going to violate anything. You're going to give it to counsel. You're not going to -- he's not going to produce it to me unless it's appropriate to produce it to me --
A Uh-huh. Okay.
Q -- from his perspective.
A Uh-huh.
Q Okay?
You've got to answer verbally.
A I understand.
Q Okay? I just want to give you -- I should probably give you this, even though you're probably aware of this. Please make sure that all your answers are verbal in nature. Don't nod your hear or say uh-huh or unh-unh, otherwise, the court reporter won't be able to take that down.
A I understand.
Q Okay. And can you estimate for me on how many occasions you have issued expert reports in a litigation?

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A It would be a guess. I would say a couple dozen, over a couple dozen, perhaps.
Q So somewhere in the mid-20s?
A Yes. But some of those have been reports under a single type of litigation, a single type of issue.
Q Okay.
A For example, I -- I-Flow. I've been an expert in I-Flow cases, and there's -- there's a number of, you know, cases going on there. So if you lump it all under I-Flow, you know, that's one thing. If I break that out, then there's a number of reports there.
Q On how many occasions have you actually issued an expert report on behalf of a plaintiff in a litigation?
A Well, I think I'll examine that tonight, just to -- it wasn't anything I prepared for. But I'll take a look at that.
Q Give me your best guess, estimate.
A Well, with the caveat that I'm not sure what happened with the report and whether he was even -- it was even submitted to opposing counsel or even to the -- to the court, a couple.
Q Okay. Any of the plaintiffs' cases in

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which you've issued a report involve -- did any of those involve allegations concerning 510-Ks?
A They may have concern -- they may have involved 510-Ks, but whether there was a primary issue, I'm thinking of one. I don't think it was the primary issue.
Q In any of the cases in which you acted as a plaintiff's expert and issued a report, was there any issue or allegation concerning material misstatements or omissions from an IFU, a patient brochure, or any advertising materials or labeling?
A Could you say that again, please?
Q Sure.
MR. MAZIE: Could you repeat that?
(The reporter read the record as follows:
"QUESTION: In any of the cases in which you acted as a plaintiff's expert and issued a report, was there any issue or allegation concerning material misstatements or omissions from an IFU, a patient brochure, or any advertising materials or labeling?")
A I seem to be focused on this one report in my mind. There were -- there were issues of advertisements and labeling.
Q Is that case still ongoing?
A No. It's been settled.

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Q Okay. Let's make sure that you look for that, that report in particular.
Did you get deposed in that case?
A No, I was not.
Q Okay. Have you ever been deposed in any case in which you were named as an expert on behalf of a plaintiff?
A Of the six, no.
Q Okay. And again, those are the -- those six times are the only times you've ever been deposed in a litigation, civil litigation. Correct?
A That's correct.
Q Okay. What percentage of your time over the past two years has been devoted to litigate -- acting as an expert in litigation?
A Well, I'd like to think I split my time 50/50 between litigation and -- and regulatory support.
Q I know you say you'd "like" to say that. I'm asking you, what is the actual split?
A Well, I don't know. I don't know specifically. I'd have to add up the hours and kind of see what exactly it is.
Q What's your best estimate as to what percentage of your time is devoted to acting as an

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expert in litigation?
A Fifty percent.
Q Okay. And what percentage of the time are you acting as an expert in a litigation on behalf of a defendant pharmaceutical manufacturer?
A A pharmaceutical manufacturer specifically?
Q Well, medical device or pharmaceutical.
A Okay.
Q Big pharma, if you will.
MR. GAGE: Objection.
A Well, I think that all six depositions include testimony on behalf of a medical device company, if that's what your question is.
Q No. I'm asking, you said that you've been retained as an expert in approximately two dozen litigations. Correct?
A Yes.
Q Okay. What percentage of those litigations in which you've been retained as an expert have been on the plaintiff versus the defendant?
A Where I've been retained?
Q Yes.
A Mostly on the defendant side, being a medical device company.
Q All right. Can you estimate for us what

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percentage of the time where you've acted as an expert or been retained as an expert in a litigation where you've been retained on behalf of the defendant, what percentage?
A Oh. I couldn't say with certainty how much actual time has been spent on defendant work versus plaintiff work. But -- but the predominant percentage would be for defendant, defendant being a medical device company.
Q 90 percent?
A Well, it would start at 80 percent, just -- that could be the case. Could be 90 percent.
Q Okay. Fair to say your best estimate is that when you've been retained as an expert in a litigation, 80 to 90 percent of the time it's been on behalf of the defendant manufacturer?
A I could look at my depositions, but three of my depositions actually have been one company -- two companies, actually, being the litigants. So even if I'm on plaintiff's side, it's been a medical device company.
Q Okay. Let's talk about -- let's do it this way: On how many occasions have you represented the plaintiff where there's been an allegation that a medical device or a -- any type of medical product or

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drug caused injury to the plaintiff?
A I don't think there's any like that.
Q Okay. So it's fair to say that --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q On how many occasions have you acted as an expert on behalf of a defendant manufacturer in litigation involving allegations that an individual was injured by a medical device, a drug, or other medical product?
A That would be I believe three of the depositions. And as far as what's pending out there, I'd have to look at the other expert reports to regain a sense of exactly what the issues were.
Q Fair to say that a hundred percent of the time in which you've acted as an --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Fair to say that in those cases in which you've acted as an expert in which there was an allegation that an individual was injured by a drug, a medical device, or other medical product, you've in every instance acted as an expert on behalf of a defendant pharmaceutical manufacturer. Correct?
A Please repeat that.

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Q Sure. Fair to say that in every litigation in which you've been involved where there's been an allegation that an individual's been injured by a medical device, a drug, or other medical product, you've acted as the expert on behalf of the defendant pharmaceutical manufacturer. Correct?
A I -- I can't say with certainty, but I believe that to be the case.
Q Okay. You've had Ulatowski Consulting, you've had Becker & Associates, and I think there's a third company you've been associated with?
Is that correct?
A Yes.
Q What company is that?
A NDA Partners, LLC.
Q Are you still affiliated with NDA Partners?
A Oh, very loosely. I'm still in the process of transferring maybe one or two contracts where I was engaged under -- by them, and they're being transferred to Becker & Associates.
Q Okay. So it's a wind-down?
A It's a wind-down.
Q Okay. And what was your relationship with NDA Partners?
A I was termed a principal, not a partner.

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Q What's the difference?
A Well, a partner has part ownership through shares or whatever the mechanism is by NDA Partners. Whereas a principal is -- I was a 1099 associate of NDA Partners that -- I guess the term identifies some significance as far as expertise or -- or whatever the case may be. I'm sure there's a -- there's a term there, some definition somewhere.
Q For what period of time did you work for or with NDA Partners?
A Well, I have it in my CV, just to -- probably not that much longer after leaving government until -- until I became an employee of Becker & Associates.
Q Okay. What type of work did you do with NDA Partners?
A Regulatory work. I was engaged in litigation under their auspices. I did some training, speeches, various things.
Q Has anyone ever advertised your services as an expert witness?
A NDA Partners on their website had me listed, I believe, with those terms, Becker & Associates. My CV is posted, so I'm sure the term's used.

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Q As a litigation expert?
A I don't -- I don't recall the exact terms, but it probably has expert witness or something in regard to that.
Q Did you at Ulatowski Consulting advertise your services as an expert witness for litigation?
A Well, the only place I advertised, if you want to call it advertising, is probably on LinkedIn, where I posted myself. But, you know, to that extent. I don't recall, actually. I haven't looked at my LinkedIn site for some time.
Q Have you ever advertised or promoted yourself as an expert witness for hire for litigation on behalf of defendant pharmaceutical manufacturers?
A I don't believe that's been any limitation in that regard.
Q Okay. So how have you advertised yourself, or held yourself out as an expert?
A By that you mean exactly what; held myself out as?
Q What you're available to do in litigation.
A Well, the only -- it's been broadly stated, expert witness in litigations. So I've been approached by attorneys for plaintiff, I was approached by Mr. Aylstock in this case to -- to work

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for plaintiff. But I was already engaged, conflicted. I had been engaged, called many times by plaintiff attorneys.
There's been conflicts, there's been issues. So I -- I will entertain any -- anybody as far as at least a first contact.
Q You've never accepted an assignment from a plaintiff lawyer in a case in which there's been an allegation that an individual has been injured by virtue of a medical product, a medical device, or drug. Correct?
A I believe that to be the case. It doesn't mean that someone hasn't approached me to -- for me to consider that.
Q You've never accepted any assignment to act as an expert on behalf of a plaintiff in a litigation in which somebody has been injured and the allegation is that there was a defect or a failure to warn with regard to a medical device, medical product, or drug. Correct?
A I believe that to be the case.
Q Okay. Now, have you ever submitted a 510-K to the FDA on behalf of a medical device manufacturer?
A Yes.
Q Okay. On how many occasions have you done

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that?
A I have to check my records at primarily Becker & Associates. That's part of what we do at Becker & Associates.
I'd say two, three times, perhaps.
Q Okay. So fair to say that your entire experience in your career in submitting a 510-K is -- you've done it approximately two to three times?
A It's -- it's a guess, but I -- it's not been a -- a large number so far. I've only been working with them for a few months.
Q How many people -- how many other people were involved in preparing those 510-Ks?
A There's a -- there's staff of assistants, associates, that assist me in preparation of portions of the 510-K.
Q On the two or three occasions in which you were involved in submitting a 510-K, were you the primary or lead person associated with the submission of the 510-K?
A I may not have been identified in the 510-K as the primary contact, if that's your question.
Q No. My question is, from your perspective, were you the senior person, the person who was the most involved and in charge of making the decisions

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for the 510-Ks that were actually submitted?
A I would be the primary person at Becker & Associates, yes.
Q Okay. As opposed to the primary person at the client?
A I guess I don't understand your --
Q Who actually submitted -- let me ask you this: Were those 510-Ks actually submitted to the FDA?
A Yes.
Q Okay. Who submitted the 510-Ks? Was it the client, manufacturer, or was it Becker & Associates?
A I -- I believe Becker & Associates filed on behalf of the client.
Q Okay. And those submissions have been made?
A Yes.
Q Okay. And were they cleared by the FDA?
A It's relatively recent. Because I -- as I said, I've just been with Becker just a few months, a few weeks. So I think they're still under review.
Q Okay. Fair to say you've never had a 510-K that you've submitted to the FDA cleared by the FDA. Correct?

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A Not to my knowledge. Although I could check up on the status of the ones submitted to see exactly what their situation is.
Q As you sit here today, you've never submitted a 510-K to the FDA that's been cleared by the FDA. Correct? To your knowledge.
A To my knowledge, yes.
Q Now, you worked at the FDA for how many years?
A Almost 37.
Q Okay. During those 37 years did you ever seek to leave the FDA and go to the private sector?
A Yes.
Q Okay. When was that, first?
A Well, I think one primarily sticks in my head, to where -- I don't even recall how long ago it was, maybe 15 years ago or so, I engaged in discussions with a consulting firm. Reached the stage of contract, but I decided to stay with the agency.
Q Okay. You can't estimate for me when that was, what decade?
A I was with device evaluation at the time, so in the '90s, perhaps; early '90s, mid '90s.
Q Okay. Did they approach you or you approached them?

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A I don't recall.
Q Okay. Aside from that one instance in the '90s, when did you next seek to leave the FDA potentially, or explore the possibility?
A Well, I would -- I would be approached by people from time to time, but as far as me responding and engaging in any discussion, it didn't occur until actually after I left the agency. I think I may have contacted NDA Partners, an associate there, just to generally talk about consulting. But we didn't engage in any negotiations. And, in fact, when I even contacted NDA Partners, I excluded myself from any dealings regarding drugs and devices at that time, market submissions or -- or anything. So just a, you know, stay divorced from any possibility of an ethical issue.
Q Okay. Aside from NDA Partners, did you contact or speak with any other company in the private sphere while you were at the FDA about potentially leaving and going to work for them?
A No. I don't recall. You know, you engage in discussions about leaving the agency, but that's not the same thing as engaging in conversation about future employment at a particular company with a particular person in a conversation. I don't think

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I've done that.
Q So is it your testimony that the only company you spoke with about the potential of joining them while you were at the FDA was NDA Partners?
A As far as I recall. Not to say there wasn't, but I just -- I can't think of anything, anybody else.
Q Mr. Ulatowski, have you ever been involved in drafting an IFU?
A At Becker & Associates Consulting.
Q Okay. You've been at Becker & Associates consulting for how long?
A Well, I was a 1099 for Becker actually for a few months longer than -- than being an employee. But in constructing the 510-Ks, for example, you know, that's one very important element of the -- of the 510-K.
Q Okay. So how -- let me ask you this: How long have you been at Becker?
A As an employee since -- it's in my CV. Maybe July.
Q Okay. And prior to July were you affiliated with Becker?
A As a 1099 consultant on occasion.
Q Okay. What percentage of your time --

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MR. MAZIE: Strike that.
BY MR. MAZIE:
Q When was the first time you did any work for Becker?
A I'd have to look at my records. I can't tell you offhand.
Q Let me ask you this: Prior to becoming a --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q When is the first time you were ever involved in preparing a 510-K for submission to the FDA?
A It was probably with Becker & Associates after I became an employee, as far as I would think.
Q All right. Well, this is obviously very recent, because you only became an employee in July, which is just a few months ago. So let me ask you this: When --
A I may have been engaged because -- I'd have to look at my records, because some things might have transitioned as I -- when I was a 1099, and then now as an employee. But I just don't recollect offhand.
Q Okay. All we're looking for is your best recollection. A lot of these events we're talking

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about happened only -- in the last few months.
So you've already testified that you think that you've been involved on two, maybe three occasions in which you were involved in preparing and submitting a 510-K to the FDA. Correct?
A Yes.
Q And my question is, when did you first start working on any 510-K for submission to the FDA in your entire career? When is the first time you ever did that?
A It may have been before I became an employee of Becker & Associates as a 1099 consultant for Becker. I have to look at my records and billing records just to see when those first hours were accounted for.
Q Fair to say that the first time you ever worked on any --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q It's fair to say that the first time in your career that you worked on any 510-K in any fashion for submission to the FDA was within the past six months.
A Well, with the caveat I just mentioned, that, you know, there may have been a portion as a

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1099 where I initiated that sort of work. But as far as exact dates, no. You know, I have to look at my records again.
Q Well, is it possible that you worked on any 510-Ks prior to 2012?
A It's possible.
Q Okay. You don't know, though, as you sit here today.
A Well, I -- I've had a lot of clients, a lot of different work. So I don't try to memorize my -- my billing records.
Q As you sit here today, you can't tell us the first time you worked on any 510-K submission. Correct?
A Not a specific date.
Q You know, though, that it was certainly in the past year and a half or so?
A It would have to be.
Q Okay. Have you ever been involved in drafting a patient brochure for any medical device or drug?
A Yes.
Q Okay. On how many occasions?
A I think the -- I think maybe once, maybe twice. So of the -- of the few 510-Ks I've worked on,

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I think one or two of those actually had a -- were over-the-counter sorts of -- or prescription with patient information, so ...
Q Okay. So you think that in your career you've actually worked on a patient brochure one or two times. Correct?
A I believe that to be the case. I'll have to review my records again.
Q And that was certainly within the last year and a half or so.
A Yes.
Q Okay. Have you ever worked as a litigation expert or consultant for Ethicon or Johnson & Johnson outside of this case?
A Not in litigation but otherwise?
Q Either.
A Yes.
Q Okay. Why don't you tell us on what -- how many occasions.
A Well, of course this -- this litigation is self-apparent. I mentioned DePuy, the deposition last week. And I provided regulatory support for J&J, a couple of J&J companies along the way --
Q Okay.
A -- in the past two years since I've been a

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consultant.
Q Okay. In the past six months, what percentage of your income --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q In the past six months, what percentage of your billings have been associated with J&J litigations? And when I say "J&J litigations," I'm referring to Ethicon or any other J&J affiliated entity, whether it be DePuy or otherwise.
A Oh, that's a -- that's difficult for me to answer without looking at my records.
Q Can you estimate for us what percentage of your billings in the past six months have been as a result of your litigation consulting with DePuy, Ethicon, or any other J&J entity?
A I couldn't hazard a guess. I don't do the billing at Becker & Associates, you know, someone else does that. I transfer my hours from my spreadsheet.
I don't know. I'd have to study my spreadsheet to see, make a -- a reasonable answer to that question.
Q Okay. Since January 1st, 2012, can you estimate for this jury the percentage -- your percentage -- the percentage of time that you've spent

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as an expert witness on behalf of a litigation in which --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Can you estimate for this jury the amount of time you've spent since January 1st, 2012, acting as a litigation expert or consultant on behalf of Ethicon, DePuy, or any other Johnson & Johnson entity?
A I -- I would be speculating. I don't -- I don't know offhand.
Q You can't give a -- an estimate to this jury as to how much time you spent for litigation consulting for J&J, DePuy, or Ethicon since January 1st?
A No. I have a lot of clients. My spreadsheet has a lot of names on it. So I -- I couldn't tell you that with any certainty.
Q How much money did you bill for -- have you billed to date for this case, for Ethicon?
A I was informed by counsel that -- unless I'm mistaken, it was something like $60,000.
Q Okay. How much do you bill per hour?
A 400 per hour.
Q Okay. And the total billings in this, case it's your testimony, are $60,000?

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A That was my understanding. I -- I never added up the hours. But I think that's what counsel stated to me at one point.
Q At what point?
A Recently. A couple -- three days ago. I think when all the records were provided, billing records by Becker & Associates, we -- somebody added it up.
Q On how many occasions have you actually testified in court in any matter, whether it be the FDA or otherwise?
A Just the one time.
Q Just the one time?
A As an FDA employee.
Q Have you ever represented in any materials that you were one of the primary witnesses for the FDA while you were at the FDA?
A That was probably the one case, in Chicago, where I testified.
Q Where did you make that representation?
A Oh, probably one of my CVs along the way, in the first -- probably on the first page. I don't recall specifically.
Q In your CV you said that you were the FDA key witness in federal court in the U.S. versus Abtox

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case, you were a contributor to many court cases, advisor to the DOJ, and FDA criminal investigations office. Is that correct?
A That's correct.
Q All right. On how many occasions were you a contributor to many court cases?
A Well, none as a witness, not testifying in court. But providing background, behind-the-scenes information, advice, counsel.
Q What does that mean?
A Well, when -- when you're working up a case that moves forward through the Department of Justice, the director of compliance has a key role in presenting the case to the government, to the U.S. Attorney, the facts of the case -- in addition to the general counsel of FDA. The facts of the case, the evidence.
You're asked questions, you're asked about key elements of the case, how -- how to present certain portions of the case, perhaps, by DOJ attorneys. So in that sense, contribution.
Q So they asked you for information and you provided it, essentially?
A Opinions, recommendations from time to time.

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Q And again, the only time you testified in court was in the U.S. versus Abtox case?
A Yeah. I don't think it was called U.S. versus -- I think it was probably U.S. versus Caputo was the exact title.
Q And when was that testimony, approximately?
A Four, 2004 or '5.
Q How many days did you testify for?
A At least a day and a half.
Q Have you ever been a party to a litigation, either as a plaintiff or a defendant?
A No.
Q Have you ever been formally or informally criticized by anyone at the FDA or outside the FDA for your work there?
A Can you repeat that?
Q Sure. Have you ever been formally or informally criticized by anyone at the FDA or outside the FDA for your work at the FDA?
A Well, that covers a lot of ground.
Criticized by whom?
Q Anyone.
A I'm sure I was criticized by some of my employees, criticized for voicing opinions, you know, criticism -- if you could define criticism.

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Q Have you ever had any type of formal criticism regarding your work while at the FDA?
A "Formal criticism" being?
Q By any body. By any body, B-O-D-Y. Not anybody, but any body, B-O-D-Y, internally at the FDA or Congress or any organization?
A Any government organization?
Q Sure.
A Formally, whatever that means.
Not that I can -- I can ever recall.
Q Have you ever evaluated adverse events reported during premarket clinical investigations and determined if these events required expedited reporting?
A Yes.
Q When?
A During my -- my tenure in device evaluation, there was a period of time when a lot of the reports, there was interaction on reporting and identification of the need for expedited reporting for deaths, certain deaths, certain serious injuries.
That role transitioned to the Office of Surveillance and Biometrics. So, you know, I mean, during the course of my tenure at FDA.
But the primary responsibility now for

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doing that is in the Office of Surveillance and Biometrics.
Q When was the -- when did you actually evaluate adverse events; what years?
A Probably when I first became a branch chief in device evaluation -- in my CV I indicate the dates -- up through almost the end of my career.
Q And on how many occasions did you actually evaluate adverse events?
A On how many days?
Q How many occasions?
A How many occasions? Innumerable.
Q Have you ever designed a regulatory strategy for a medical device?
A Yes.
Q When?
A As an employee of Becker & Associates, as a principal for NDA Partners.
Q Okay. On how many occasions have you designed a regulatory strategy for a medical device?
A Half a dozen times.
Q When is the first time you ever designed a regulatory strategy for a medical device?
A Probably NDA Partners, discussions regarding a combination product, how to approach

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design, how to approach the regulatory process for them, a particular combination product. I think that's -- that comes to mind as being the first time.
Q When was that?
A After I left the agency, maybe mid summer last year.
Q So sometime in the past 12 to 15 months is the first time that you designed a regulatory strategy for a medical device. Correct?
A Thereabouts.
Q Okay. Have you ever designed a clinical trial or written a clinical trial protocol?
A No.
Q Have you ever evaluated and assessed clinical trial data to determine product safety?
A Yes.
Q When?
A During my tenure in the investigational device office as an employee and then as director. During my tenure in device evaluation, evaluating products over the course of my tenure, primarily in those areas.
Q Have you ever evaluated and assessed clinical trial data to determine product defectiveness?

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A Yes.
Q Same answer?
A Same answer.
Q Have you ever written medical device labeling for a medical device company?
A Well, I think you already asked that. I -- yes, I've constructed IFUs.
Q Okay.
A We talked about patient labeling. Those are forms of labeling.
Q Have you ever participated on a medical device product development team at a company?
A Yes.
Q When?
A Well, fresh in my mind, I'm on a team that started on Monday with a new product.
Q Okay. Aside from the team you started with a few days ago, when else have you ever participated on a medical device product development team at a company, or for a company?
A Well, in the broadest sense, as -- as you're part of the formulation of testing and design control related activities, we talked about 510-Ks, but really the discussion regarding the products precedes the 510-K submission.

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You are part of the team and conversation regarding -- and decision-making regarding what sorts of tests need to be accomplished and other aspects of the development program.
So when we talk about 510-K submissions, that's part of the whole process.
Q All right. So your -- your -- it's your testimony that your participation on a medical device product development team is limited to those two or three occasions in which you have been involved in the submission of a 510-K over the past year and a half.
Correct?
A And -- and the most recent activity.
Q Which is you just got named three days ago to a team?
A That's correct.
Q Have you ever done bench testing for a medical device?
A Not -- not as a consultant or employee of Becker & Associates.
Q I'm asking ever in your career, have you ever done bench testing for a medical device?
A I participated in some evaluations in our science and engineering -- in FDA's science and engineering laboratories, evaluating some issues

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regarding devices; forensic sorts of studies.
Q On how many occasions?
A I can't tell you specifically. A few times.
Q Okay. Have you ever done any type of performance testing for any medical device?
A Not as a -- as a consultant or employee of Becker & Associates.
Q I'm not limiting my questions to Becker & Associates. I'm asking you, in your career have you ever done any type of performance testing for a medical device?
A Well, I think some of those laboratory exercises were related to performance, safety and performance.
Q And you're talking about the couple of times that you might have done it at the -- over your 37 -- 37-year career at the FDA. Correct?
A For medical devices, yes.
Q All right. And again, you weren't the primary person doing the performance testing.
A No, I was not the primary laboratory.
Q Have you ever developed a standard operating procedure for a medical device company?
A Yes.

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Q When was that?
A More than half a dozen times. It's probably now getting to a dozen times, probably.
Q Okay. Have you ever performed an FMEA?
A Only in coursework in college.
I've -- well, actually, I did -- I did a large risk-management work task for -- for a large pharmaceutical/medical device company. So that took a great deal of time. And part of that involves FMEAs, risk reports, related issues.
So, I mean, that's a long answer. The short answer is yes.
Q Okay. Outside of college, have you ever been involved in performing an FMEA?
A Well, what I did is -- I guess the short answer is yes. I'll explain.
I -- as I said, I constructed and participated with a large pharmaceutical/medical device company in -- in creating their risk-management program. And part of that included formatting and creation of their risk-management documentation, which included FMEAs.
Q And when was that?
A Last year.
Q Okay. That's the only time you've been

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involved with an FMEA?
A No. It -- in examining design control information, commenting, critiquing for companies, the issue comes up from time to time, FMEAs; their construction, their adequacy, their usage in the company. The SOPs surrounding FMEAs.
Q Have you ever done any type of consulting for tobacco companies?
A Yes.
Q When?
A Last year.
Q Which company were you affiliated with at that time?
A Altria.
Q What's Altria?
A It owns Philip Morris and other companies.
Q No, I was asking which company you were affiliated with, yourself; Ulatowski Partners --
A Oh. Ulatowski Consulting, LLC.
Q Ulatowski. Okay.
What type of consulting did you do for tobacco companies?
A Well, it's very little, actually. Just introductory sorts of conversations. I think there was a training program I participated in. That's been

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about it.
Q Fair to say you were doing about 15 hours a month for the tobacco companies?
A It wasn't very much. It was not many hours.
Q Have you ever testified that you were performing about 15 hours per month of work for tobacco companies?
A I may have. There weren't many hours. And there haven't been many hours for many months.
Q At Becker Consulting have you done any work for tobacco companies?
A No.
Q At NDA Consulting did you do any work for tobacco companies?
A No.
Q Did NDA Consulting tell you they did not want to be involved with any type of consulting for tobacco companies?
A Yes.
Q And because of that, you did the consulting on your own through Ulatowski Consulting?
A Yes.
Q Okay. You say in your CV that you were at some point a primary reviewer of 510-Ks?

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A Yes.
Q Okay. When was the last time you were a primary reviewer of 510-Ks?
A Probably when I became director of compliance.
Q When is that?
A 2003.
Q For what period of time were you the primary reviewer of 510-K submissions?
A When I first became branch chief within device evaluation until I became director of compliance.
Q What's the time period?
A I could look at my CV. I would say 15, 16 years.
Q Okay. And how many 510-Ks -- can you estimate for me how many 510-K applications you reviewed?
A Impossible to say. Innumerable.
Q Okay. What percentage of the time did you clear 510-Ks, approximately, as opposed to not clearing them?
A I would say the majority were of the results of the review, formal results of the review, were substantial equivalence. But I might add that

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during the course of review of the 510-K, many submissions fall away for one reason or another. And so if you're asking how many were submitted for review and how many were then cleared, you know, that would maybe be another answer.
Q Well, that's my question. My question is, what percentage of the time 510-Ks were submitted for your review while you were at the FDA where you did not ultimately clear the product, or the application?
A Did not ultimately clear.
Q Yep. Percentagewise.
A A third to maybe more.
Q Okay. So your best estimate is that approximately a third to, say, 40 percent of the time, say 30 to 40 percent of the time, where you were the primary reviewer of a 510-K, the product ultimately was not cleared by the FDA. Is that fair to say?
A It varied from point to point, from type of device to type of device. To aggregate it, you know, there would be an error bar in that number.
Thirty, forty.
Q Percent?
A Yes.
Q Were not cleared?
A Were not ultimately cleared by the agency.

Q Okay. Have you ever found a company to be in noncompliance in marketing and misbranded an adulterated product because of failure to obtain a 510 -- 510-K clearance?
A I've been the signatory on warning letters where that was a charge.
Q How many occasions?
A I -- I have no way of guessing on that. Several.
Q Several or numerous?
A Whatever the definition of numerous is. Perhaps.
Q More than 20?
A Over the course of eight years, perhaps.
Q Have you ever found a company to be in noncompliance due to NDR reporting issues?
A Yes.
Q How many occasions?
A Likewise, numerous.
Q Okay. Have you ever written or presented on the subject of whether -- whether to submit a 510-K is a good-faith standard?
A Well, I guess you'd have to clarify for me. I mean, first of all, re -- restate it.
Q Sure. Let me back up.

Is it your position that whether or not to submit a 510-K is a good-faith standard on the part of the manufacturer or is it a strict liability standard?
A Well, I'm not a lawyer. So let me just answer you this way: I think that when I assess how one comes to conclusions regarding whether to submit a 510-K, I'll look at the process that they engaged in in making that decision. And seeing what -- based on the evidence, the testimony, documents, exactly what they did.
Now, if you want to characterize that as good faith, that's up to you. But, I mean, that's -- that's what I do.
Q If the FDA determines that a product was not substantially equivalent, but the manufacturer did not submit a 510-K, do you agree it doesn't matter whether or not the manufacturer was acting in good faith, the manufacturer is in violation of the regulations. Correct?
MR. GAGE: Objection.
A Please -- please repeat that.
Q Sure. Do you agree that if the FDA determines that a product which has been marketed without a 510-K is not substantially equivalent to another product, predicate product, that in that

instance the manufacturer has been marketing and selling a misbranded and adulterated product, regardless of whether or not the manufacturer acted in good faith in its determination of whether or not a 510-K should be submitted?
MR. GAGE: Objection.
A Well, if you -- you preface by FDA. FDA determines through a 510-K submission, because that's the only way they would determine it being substantially equivalent or not substantially equivalent, determines a product to be not substantially equivalent, then the product has to be -- cannot be marketed.
Q Okay. And if the product was marketed before that determination, and before the submission of the 510-K, then that marketing of the product would be illegal. Correct?
MR. GAGE: Objection.
A FDA's determination of nonequivalence is an agency determination. And at that point FDA may instruct, through the office of compliance in all likelihood, that the product needs to be removed from the marketplace.
But one caveat is is that a finding of not substantial equivalence is not -- can be appealed. A

company can proceed to various levels within the agency to appeal the decision, and FDA could conceivably continue to allow enforcement discretion.
MR. MAZIE: I'm going to object and move to strike as nonresponsive.
BY MR. MAZIE:
Q My question is, if you have a situation where a manufacturer elects not to submit a 510-K, markets a product, ultimately decides to submit a 510-K, and then there's a finding of nonsubstantial equivalence as determined by the FDA, is it fair to say that the product before the submission of the 510-K was being illegally marketed?
MR. GAGE: Objection.
A I think that would probably incur the need for a process to establish the charge, and to then have the product removed through a process.
Q Do you agree that the product as it was marketed before 510-K clearance was misbranded and adulterated?
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Do you agree that the product before submission of the 510-K --
MR. MAZIE: Strike that.

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BY MR. MAZIE:
Q Do you agree that under the scenario I just gave you, where a manufacturer submits a 510-K after marketing a product for three years, and then there's a determination by the FDA that the product is not substantially equivalent, that prior to that determination of nonsubstantial equivalence, that the product was misbranded and adulterated by definition?
MR. GAGE: Objection.
A I think there would -- I don't think it's an automatic designation. I think there would have to be a process of -- then determination and charge against the product.
Q Why is that?
A Well, it's just because of the fact that the process of -- of finding a not substantial equivalence may have so many twists and turns to it. I mentioned the appeal process. I mentioned the -- the finding -- the -- the technical and scientific basis for the finding of not substantial equivalence. Is it valid, is it appropriate? What is the reason for nonequivalence, can it be remedied -- easily remedied?
I don't -- I think it would -- how this would unfold is, depending on the circumstances, each

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case being its own circumstance, it would probably incur a process of evaluation, whether the agency would declare the product adulterated and misbranded and to move to have the product removed from the marketplace.
MR. MAZIE: Okay. We have to change the tape.
VIDEO SPECIALIST: The time now is 11:02. We are going off the record. This is the end of Disk Number 1.
(Short recess.)
VIDEO SPECIALIST: The time now is 11:11. We are back on the record. This is the beginning of Disk Number 2.
BY MR. MAZIE:
Q Mr. Ulatowski, what I'm trying to get at is, I know you talked about the fact that under the scenario I gave you there can be an appeal process, there can be a, you know, examination on a technical and scientific basis. My question is, if it is ultimately determined, after appeals, after whatever, that a product which was marketed prior to submission of a 510-K, that the product was not substantially equivalent to a predicate product, under that scenario will you agree that the product was adult --

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adulterated, misbranded, and illegally marketed?
MR. GAGE: Objection.
A Well, again, I think, in my experience, that charges are levied after a process of evaluation by the office of compliance, taking facts into consideration, and then formally rendering charges.
Q I'm not talking about criminal charges.
A No, I'm not talking about -- violations of law.
Q And what goes into that analysis of whether or not to led -- levy charges?
A Evaluation of the evidence, evaluation of the -- the record, evaluation of the statements of knowledgeable people within the agency or connected to the agency.
Office of compliance doesn't automatically do anything; it -- to be fair and provide for due process for the parties, knowing that anything and everything could end up in court, that there's always a process incurred, as far as evaluating the facts.
Q Is it your testimony that in order for there to be a determination that something is adulterated or misbranded while being marketed that there needs to actually be charges levied?
A There has to be a determination through a

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process that the violations exist, that the violations are appropriate, are supportable, based upon the evidence.
Because, as I said, whenever the office of compliance states a violation of law, be it in a warning letter or injunction or whatever the case may be, you've got to have your ducks in order.
Q Let me ask you this: If Ethicon in this instance created a new product that clearly, even in its own opinion, was not based on a predicate at all, any predicate product, and decided just to sell it without submission of any type of clearance or approval by the FDA, would that product be legally marketed?
MR. GAGE: Objection.
A Well, I think, again, the process would occur. Evaluation -- obtaining and evaluating the evidence, discussing the issues internally. Because again, you've got -- you've -- everything and anything can end up in federal court, where the company or whoever sues the government to say you acted arbitrarily and capricious, or whatever the case may be. You've got to have your ducks in order in every single instance.
So it's an evaluation of evidence, expert

opinion, so on and so forth, before you put pen to paper to say adulteration and misbranding.
Q All right. So you think that it's not something automatic in the law, whether something is adulterated or misbranded?
A That's --
MR. GAGE: Objection.
A Well, I think what I'm saying is is not automatic in terms of there is a process that ensues in order to -- the end result being whether or not a violation is -- is stated.
Q All right. So if I go out, I create my own company and I start selling a product, a medical device that I create in my garage, and I don't make any submissions to the FDA, and the FDA learns about it three years after I'm selling this medical device, for those -- even before FDA takes any action, are you telling me that by definition my sale of that medical device is not adulterated or misbranded?
MR. GAGE: Objection.
A It may not be. I'd have to know the facts, the evidence, the circumstances. That's what I did in compliance. We -- before we rendered any violations, you had to have the evidence, the data, the information, the package. Because the next step was

the court. And, you know, you don't want to get thrown out.
Q Right. Let's then take my scenario further. I create this medical device in my garage, it's not based on any other product, and I sell it for three years. The FDA finds out about it, makes a determination that the product is adulterated and misbranded and being illegally sold, there are no appeals, and there are -- is no further legal action taken in the courts by me.
Under that scenario, is the product misbranded and adulterated and illegally marketed?
MR. GAGE: Objection.
A Well, what you -- I mean, that's -- you had a lot of ands and alsos in there. But as far as what I heard, the elements of FDA has made the determination, I believe, based on evidence, the facts, whatever needs to be brought to bear in order to construct the basis for the charge, the violation, the violation then being confirmed and concurred by compliance, confirmed and concurred by the general counsel of FDA, and then you move to take enforcement action.
Q Under that scenario, is the product adulterated, misbranded, and illegally marketed by me?

MR. GAGE: Objection.
A If there's going to be an enforcement action, yes; there's been a determination at that point in time, if FDA has formally gone through that process, formally made a statement, a decision, through the appropriate channels and course of review and evaluation, decision being formally made by the appropriately designated people that this product is adulterated and/or misbranded, then you move to enforcement.
Q Okay. And enforcement would include ensuring that I take the market off the -- the product off the market?
A Well, you're -- depending on what the situation is. There's -- there's several remedies; injunction or seizure, for example.
Q Okay. Let's assume that I make this product, this medical device, out of my own garage, it's not based on any other product, FDA finds out about it and makes a determination that the product is adulterated and misbranded and illegally sold, but it determines that I just didn't know what I was doing and I was acting in good faith.
Does that change the fact that the product is adulterated and misbranded and illegally sold?

MR. GAGE: Objection.
A Well, I don't -- I don't know what to make of the statement "good faith."
What FDA would do, in my role as compliance director, for example, would be to evaluate the facts. What are the facts? What's the evidence that's brought to bear? What's the testimony of -- statements of the appropriate people in regard to this particular case? What's the inspection findings?
So what's on the table, what can I conclude based upon everything before me in order to make -- render a conclusion that there's -- there is a violation? What is the proper violation?
Q What -- what's --
A Regardless, I think perhaps of -- of what the manufacturer may have thought at that point in time, the evidence being brought to bear, decision by compliance being rendered, finding of adulteration and misbranding.
Q What's on the table is that I was stupid and I thought I didn't need to get approval from the FDA. Okay?
So let me just give you this scenario: Out of my garage I create a medical device, because I don't think -- I'm acting in good faith, but I don't

know or think that I need to get approval from the FDA. The FDA finds out about this six months later, and immediately says, You need to stop selling it, which I do. And that the product when it was sold was misbranded and adulterated.

Under that scenario do you agree, regardless of whether or not I acted in good faith, that the product as it -- when it was sold was adulterated and misbranded? That's my simple question to you.

MR. GAGE: Objection.

A Well, it's a simple question, but -- but the answer is, you know, I'll bring to the table, again, this process, a determination.

Q Determination is made, in my scenario. FDA makes the determination.

A If FDA has rendered, through appropriate process, based upon appropriate evidence, the product is adulterated and misbranded, and then it moves to take an enforcement action, the manufacturer says, Okay, well, I was wrong, stop selling. Those are scenarios that occur.

Q My question is --

MR. MAZIE: I'll object and move to strike.

BY MR. MAZIE:

Q My question is, and what I'm focusing on, it doesn't matter whether I'm acting in good faith or not in the end as to whether or not a product is adulterated or misbranded and illegally sold.

Correct?

MR. GAGE: Objection.

A Well, you used the term "good faith." I mean, in what -- in what sense of good faith?

Q I thought that I didn't need to go to the FDA and get clearance for the product. I didn't think I needed any type of approval to sell the product. I created it in my garage, and I went out and I sold it. When I found out by the FDA that I had to have clearance or approval, I stopped selling it.

The determination by the FDA that the product was adulterated and misbranded stands, regardless of whether or not I was stupid enough to think I didn't need FDA clearance or approval even though I was acting in good faith. Correct?

MR. GAGE: Objection.

A Well, part of the evidence would be -- based upon evidence collected during perhaps inspection, would be what was the process this person used; what did -- why did they rely on -- what reliance did they use to make them believe they could

go to market? What is their -- what is their process? What's their documentation? What's their thinking before they went to market.

Q Why does that matter?

A It has everything to do with the issue. Because FDA is evaluating -- first of all, wants to be fair. Wants to understand the parameters of the situation. Wants to understand the thinking of the submitter.

Because, again, any case can end up in court before a judge. And you've got to have all the bases covered and ducks in order. You've got to understand their thinking, their reasoning, their documentation, based upon evidence collected through inspection or otherwise.

Q So you can't answer the question as to whether or not somebody who is marketing a product which is determined to be adulterated and misbranded by the FDA, whether or not the product doesn't become -- that's --

MR. MAZIE: Strike that.

BY MR. MAZIE:

Q You can't give us an opinion as to whether or not, if the FDA issues a decision that a product that was being sold was adulterated or misbranded,

whether or not that becomes reversed in -- somehow or mitigated if the manufacturer of that product was acting in good faith.

MR. GAGE: Objection.

A Well, I -- I mean, I'm not -- I mean, good faith, the term "good faith" sort of is undefined.

I think they -- FDA has, again, collected the evidence, regardless of whether the manufacturer calls it good faith or whatever they call it, what does the evidence show; what did they believe, what's the basis for their belief? Basis based upon regulation and law, and process and procedure.

And then FDA, collecting that, assessing that, making a decision, the appropriate people making the decision at FDA that, well, there's no adulteration and/or misbranding.

MR. MAZIE: Object and move to strike.

All right. Why don't we mark this as the next exhibit.

(Ulatowski Exhibit 6 marked for identification, to be attached to the transcript.)

BY MR. MAZIE:

Q I show you what's been marked as Ulatowski 6. Do you know what this is?

A Yes.

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Q What is this?
A This is what every employee who leaves the agency is given upon the completion of their service.
Q Okay. And does it apply to you?
A Yes.
Q Okay.
A Portions of it apply to me.
Q Okay. Which portions?
A Might be easier to ask me which portions do not.
Q All right. Which portions of this document don't apply to you?
A The ban on -- well, they all I guess fundamentally apply. But real -- realistically what applies -- what doesn't apply is the ban on trade or treaty negotiation activities. That's just not what I do.
Q Okay.
A And the compensation limitation, that's not what I do. Disclosure of procurement information, again, that's not what I do.
Because of the amounts, the one-year ban on contractor compensation doesn't -- doesn't apply. And in the lower part, the one-year foreign entity provision, that's not -- that's not what I do.

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So those elements. So it looks like 50/50 I guess, once we look at it.
Q Forty-five CFR Part 2 applies to you. Correct?
A The testimony and production of documents, so on and so forth?
Q Yes.
A Yes.
Q All right. And what is your understanding of that provision?
A This is -- it's my belief, as instructed by the ethics office, that this concerns disclosure of confidential and trade secret information, specific deliberations that are not in the public realm in doing consulting work or -- or whatever the case may be.
Q It's fair to say that you're not entitled in this or any other case to provide testimony concerning information acquired during the course of your official duties or because of your former position with the FDA?
A Yes, and --
MR. GAGE: Objection.
A -- and that concerns confidential trade secret information, other deliberations that is not

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public information.
But any information gathered from documents applied in litigation is -- is not subject to that.
Q Any deliberative process within the FDA is covered by this. Correct?
A Until such time that that deliberative process ends.
Q Okay. So it's your understanding that if you worked on a evaluation of a product at the FDA, and then you left the FDA, you were -- you're entitled to provide testimony or produce documents concerning that deliberative process at the FDA?
A If that -- if that issue has closed, I think I probably would be able to.
Q Have you ever done that in any case?
A No. When I've talked about FDA, I've talked about generally known or understood policies, procedures, public documents, things of that sort.
Q Were you involved in any way, shape, or form in the evaluation of the Prolift, or the Prolift +M?
A Not in device evaluation.
Q At any time while you were at the FDA were you involved in the evaluation or interaction with Ethicon concerning the Prolift?

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A I don't believe so. There -- it may have occurred in terms of any inspection that might have occurred of the facility. But that's kind of a indirect connection. But not directly, as -- as I recall.
Q As you sit here today, do you have any knowledge of any of the deliberations at the FDA or reviews or interactions between the FDA and Ethicon concerning the -- the Prolift outside of what you've read in this litigation?
A No, I don't think I had any connection in the Prolift. It was a -- in device evaluation. It was a different division where I worked. In compliance there was never any enforcement action or anything of that sort.
So short answer is, I don't think I've -- nothing came -- comes to mind of any connection, discussion, interaction.
Q And you have no special knowledge of anything that occurred at the FDA, while you were at the FDA, concerning the Prolift?
A I don't believe so.
Q Have you ever spoken to anyone at the FDA concerning their interaction with Ethicon concerning the Prolift?

A I don't think so.
Q What's the purpose of the FDA?
A To help protect the public health, ensure the public health.
Q Is one of the FDA's mandates to prevent the marketing of misbranded or adulterated medical devices?
A Well, specifically as you bore down under ensuring compliance with laws and regulations. I mean, that is a prohibition.
Q My question to you is, is one of the FDA's mandates to prevent the marketing of misbranded or adulterated medical devices?
A That's an element of their mandate, of their responsibilities.
Q Do you agree that the FDA seeks accountability and a voluntary commitment to compliance but stands ready to enforce the law?
A Yes. Voluntary compliance is -- is discussed in the quality system regulation, for example. And it will enforce a law when necessary.
Q Do you agree that the FDA should use the enforcement at its disposal to help protect the public health from medical devices violating the law?
A Can you say that again, please?

Q Sure. Do you agree that the FDA should use the enforcement at its disposal to help protect the public health from medical devices which violate the law?
A When necessary, yes. And upon determination that there's a violation.
Q Do you agree that if -- even if a manufacturer of medical device maintains compliance with FDA regulations, it doesn't ensure quality of the device?
A You'll have to say that over again, please.
Q Sure. Do you agree that even if a manufacturer of a medical device maintains compliance with FDA regulations, that doesn't necessarily ensure that the device is a quality device?
MR. GAGE: Objection.
A Well, I think, for example, the compliance with the quality system regulation helps to ensure the quality of the product.
MR. MAZIE: Why don't we mark this.
(Ulatowski Exhibit 7 marked for identification, to be attached to the transcript.)
BY MR. MAZIE:
Q Have you seen this document before?
A Perhaps. I would -- I don't know. I would

have to look at this a little further.
Q Take a look at it. Tell me if you're quoted in it.
A I see my name referenced in it. It refers to a panel meeting.
Q Where you actually speak. Correct?
A I haven't gone through the entire --
Q Okay.
A I see -- I see where I spoke.
Q Okay. Do you recall when you gave this --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Do you recall giving this presentation?
A I'd have to look through it just to recollect.
Okay. I see. We're talking about just the first document.
Q Do you recall this?
A Well, I see it. You know, it comes to mind, I suppose, but.
Q Okay. All right. Why don't you turn to the -- let's see, one, two, three, four, five, six -- seventh page.
A Beginning with?
Q In the bottom, it says Mr. Ulatowski,

second sentence: Once is product is approved, made commercially available, there are physician and healthcare facility reporting requirements that are in place. Do those requirements play out in terms of types of reports we ought to be seeing? No. The reporting system is that we don't -- I'm sorry. The reporting system is there, but we don't often see all the reports that should have been submitted. That is a recurring deficiency with manufacturers and with the physicians.
Did I read that correctly?
A Yes.
MR. GAGE: Objection.
BY MR. MAZIE:
Q Do you agree with that, that the FDA, in your opinion, was seeing a recurring deficiency with manufacturers and others that they weren't reporting all adverse events?
MR. GAGE: Objection.
A Well, based upon a couple of studies, the -- in terms of MDR reports, for example, underreporting is a phenomenon.
So as far as recurring deficiency, and with physicians not reporting certain events, that is the case in terms of underreporting.

Q Okay. So just so we're clear, it's been studied and it's been accepted by the FDA that manufacturers underreport their adverse events for their medical devices and other products. Correct?
MR. GAGE: Objection.
A There have been report studies and conclusions that there is underreporting. The studies are somewhat dated, so the degree of underreporting can be argued.
Q You've held that opinion, that manufacturers underreport the adverse events they have for their products. Correct?
MR. GAGE: Objection.
A As a -- as a general population, meaning manufacturers, there's underreporting.
Q All right. Device manufacturers we're referring to. Correct?
A Yes.
Q Yeah. Do you agree that the violations of FDA laws and regulations, whether they be intentional or unintentional, are unacceptable?
A Are we reading from somewhere here?
Q I'm asking if you agree with that proposition.
A Can you say it again, please?

Q Sure. Do you agree that violations of the -- of FDA laws and regulations, whether intentional or unintentional, are unacceptable?
A Assuming that the violations have been determined through the process I've been talking about. Violations should be reduced. So the short answer is yes, with that caveat.
Q All right. So even if there's an unintentional violation of an FDA law or regulation, that's still unacceptable and a violation of law?
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Even if a device manufacturer unintentionally violates FDA laws and regulation, that's something that's unacceptable to the FDA. Correct?
A It's something that needs to be addressed. Now, what's the reason for that? How can that be mitigated? Maybe it's caused by FDA through some means.
Q All right. Let's go to -- there's a letter in here, Food and Drug Administration Enforcement Strategy, about a third of the way through?
Do you see it?
A Uh-huh.

Q You're one of the signatories to this?
A Yes.
Q And the last sentence says as follows: "Violations of FDA laws and regulations, whether intentional or unintentional, are unacceptable and may be addressed civilly and with criminal sanctions."
Do you agree with that statement?
A I signed off on that. And I think that whether or not those violations result in enforcement action, that process has to be incurred as far as the evidence brought forth.
Q Mr. Ulatowski, do you agree with the statement you made in this presentation that violations of FDA laws and regulations, whether they be intentional or unintentional, are unacceptable?
A Short --
MR. GAGE: Objection.
A Short answer is yes. I was a signatory to this document. But with the caveats I mentioned.
MR. MAZIE: I'm going to move to strike as unresponsive as to the caveats you mentioned.
BY MR. MAZIE:
Q Again, do you agree with the statement that you stated here, that violations of FDA laws and regulations, whether they be intentional or

unintentional, meaning by mistake, are unacceptable?
Do you agree with that?
MR. GAGE: Objection.
A I think I said yes already.
Q I'm going to ask you to turn to -- let's see, one, two -- another couple of pages to the page where it says Compliance.
A Where are we at now?
Q Compliance.
A Yeah. Got it.
Q Do you agree that the FDA seeks accountability of voluntary commitment to compliance, but stands ready to enforce the law when necessary?
A Yes.
Q Okay. I'm going to ask you to look, there's an article attached at the end of this document, seven-page article. I ask if you're familiar with this article?
A This James Dickinson one?
Q Yes.
A Okay.
Q Do you recall that article?
A No, not -- I'll have to read through it. Let me ...
Okay.

Q Do you recall the -- a Steris System issue back in 2008?
A Generally.
Q Do you recall that there was a determination in May of 2008 that the SS1, which is a device, had been so significantly modified from the predicate product that it was adulterated and misbranded and, therefore, illegal?
A Oh, I have to review the record to see if that was a warning letter or something in that -- to that effect. Probably was.
Q Okay.
THE WITNESS: I think I'm trapped here, by the way. Okay.
BY MR. MAZIE:
Q Do you have any recollection of the -- of the SS1, Steris System 1?
A Not in any detail, but generally.
Q Okay. You can put that away.
Have you ever taken the position at a presentation that there's an amazing lack of appreciation of the value of design controls and risk management at device manufacturers?
A Is it -- is it possible? Yes, it's possible.

Q Oh. Have you ever had that opinion, that there's been an amazing lack of appreciation of the value of design controls and risk management at device manufacturers?
MR. GAGE: Objection.
A I'd have to see the context of that statement.
Q Okay.
MR. MAZIE: Let's mark this.
(Ulatowski Exhibit 8 marked for identification, to be attached to the transcript.)
BY MR. MAZIE:
Q Are you familiar with this document?
A I don't see where I gave this.
I don't recall where I gave this, but I see it.
Q Well, you gave this within the last two years. Correct?
A Evidently, yes.
Q And you don't -- as you sit here today, telling this jury, you don't recall giving this presentation in the past two years?
A Well, I -- I give many training programs, discussions, talks.
Q Let's look at the second-to-last page.

First bullet.
Have you, in this presentation --
A Where are we, on the same page?
Okay.
Q Have you taken the position that there is an amazing lack of appreciation of the value of design controls and risk management at device manufacturers?
MR. GAGE: Objection.
A I see the statement. But I think you have to understand the context of this. The context is, I'm a consultant who works for a consulting firm, speaking to potential clients regarding their beliefs in regard to their own procedures, and trying -- trying to instill in them the need for support and collaboration with our consulting firm.
So I wasn't there to say everything's fine, you don't need us; I was there to identify that these things are not simple, in all likelihood you need some help.
Q I'm not asking you what your motivation was. I'm asking -- you weren't lying in this presentation, were you?
MR. GAGE: Objection.
A No, I don't think I was lying. But I think I was making a point related to what I just stated.

Q Have you taken the position in a presentation to clients that there's an amazing lack of appreciation of the value of design controls and risk management at device manufacturers?
MR. GAGE: Objection.
BY MR. MAZIE:
Q True or false?
MR. GAGE: Objection.
A Well, it doesn't quite say -- I made the statement. But what are the parameters of that statement, how many manufacturers, what type of manufacturers, what -- so -- I made the statement.
Q You -- okay. You've taken the position in presentations to clients that there is an amazing lack of appreciation of the value of design controls and risk management at device manufacturers. Correct?
MR. GAGE: Objection.
BY MR. MAZIE:
Q You've taken that position. Correct?
A That -- in regard to the context of the discussion after being a consultant for a few months, working with clients who come to you because they're in trouble.
And so the people I interact with are not people who are fine with the agency, great

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inspections, wonderful procedures. The people I deal with, in terms of regulatory support, are people who are in trouble.

Q Always?

A Pretty much.

Q Okay. And you consult for J&J. Correct?

A Regulatory, just one company.

Q So that company I guess is having some problems with the FDA not doing things correctly?

A That's correct.

Q Which company is that?

A Well, I'm just thinking whether I can disclose that.

MR. GAGE: Let me just say, if that's the issue, then I would ask you to make sure of that determination before you disclose it. In other words, don't guess as to whether you can disclose that. If that's something that you believe may be confidential, we can go research it, investigate it, and come back and let David know.

THE WITNESS: I'd -- I'd rather research it, because these contracts are very -- you know, I'm not a lawyer. But if something's in the contract where -- you know, I don't want to violate that.

BY MR. MAZIE:

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Q All right. Nevertheless, nevertheless, you are a consultant for one of the J&J companies who has had a history of -- of not doing things correctly vis-à-vis the FDA and its -- its compliance with FDA regulations. Correct?

MR. GAGE: Objection.

A Yes, based upon warning letters.

Q And at least as to that J&J company, and other companies that you represent, you found that there's an amazing lack of an appreciation of the value of design controls and risk management.

Correct?

MR. GAGE: Objection.

A Within the context of the people I work with are in trouble to begin with.

Q Okay. You can put that away.

Have you ever taken a position that the FDA during your tenure was understaffed?

A Did I ever make a public pronouncement about that?

Q Did you ever have the opinion. Did you ever have the opinion that the FDA, while you were there, was understaffed and undermanned?

A Did I ever have a belief of that?

Q Yeah.

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A In my tenure at FDA?

Q Yeah.

A Well, I don't know any manager who doesn't -- doesn't want more people. That's kind of, you know, a given. And just every year we would have opportunity to negotiate within the center for devices the allocation of resources.

And so it was never to your benefit to be arguing that you're just fine, you don't need anybody -- anybody. You wanted to be staffed up as much as you can be.

Q I'm not asking about what positions you take -- took vis-à-vis negotiations. I'm asking you in the past -- in the ten years leading up to your leaving the FDA, did you have the opinion that the FDA was undermanned and understaffed?

A FDA as a whole? I don't know if I ever stated that opinion to anyone as a whole. I was concerned with my office, my operations, or other offices that assisted me in my operations. More is better.

Q Fair to say on any given day a quarter of the people at the FDA were either on leave or in training or traveling?

A That's part of the life in any

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organization, that those employee statuses exist.

Q Answer my question. My question is, is it fair to say that on any given day, 25 percent of the people at the FDA were either on leave or in training or traveling. Correct?

A I may have made that statement based upon whatever the basis was. The context being ever changing as far as resources and allocation of resources and time reporting, it was probably -- if I made the statement, it's probably based on some time reporting report that -- within FDA. It was --

Q It's an accurate statement. Correct?

A Well, I don't know if it's still accurate. Was it accurate on that date when I wrote that, based upon time reporting? Probably was.

Q Okay. So at least as of last year, it was your opinion that on any given day, 25 percent of the people at the FDA were not working on FDA matters; they instead were on leave, in training, or traveling.

Correct?

MR. GAGE: Objection.

A Well, in training certainly is extremely important for federal employees. On travel? On travel in respect to you're traveling to an inspection, you know? Understanding the context and

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the depth and breadth of that statement, you have to take all those things into account.
Q You've taken the position that on any given day 25 percent of the people at the FDA were either on leave, in training, or traveling. Correct?
A If I made that statement, the statement is as it is.
Q Okay. And you also have taken the position and made the statement that half of the most -- half of most centers at the FDA do work on a daily basis unrelated to product approval or clearance. Correct?
A Well, looking at -- at the total number of employees in a center, the numerator then being how many people are in device evaluation, you can come up with a ratio.
Q I'm asking, have you taken that, have you made that statement?
A I may have made that statement.
Q And the statement is that half of most of the centers at the FDA do work on a daily basis that's unrelated to product approval or clearance. Correct? You've made that statement at a presentation?
MR. GAGE: Objection.
A Based upon the not understanding, knowing the context, and based upon the simple derivation of

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that sort of number, that may well be the case.
Q Mr. Ulatowski, can we agree that it's been documented --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Has it been documented by the FDA that over the past ten years the CDRH received 4,000 device applications per year?
A Repeat that, please.
Q Sure. Has it been documented by the FDA that over the past ten years CDRH received 4,000 device applications each year?
A Well, it sounds like an average, because the numbers go up and down. It includes 510-Ks, PMAs, PMA supplements. I don't know. It depends on the source of the information.
Q Does it sound correct to you?
A If we're talking 510-Ks and new PMAs per year as an average over ten years, I probably have to look at some device evaluation reports. It may be accurate.
Q In your opinion, in the five years leading up to your retirement from the FDA, was there enough staffing to examine and review all the 510-K applications that were received by the FDA?

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A Well, in the last five years I wasn't in device evaluation, so you would probably have to ask the device evaluation director that question.
Q Okay. When was the last time -- the last time you were involved in 510-K review was in 2003?
A Yes.
Q Okay. So you have no opinion as to whether or not the FDA was properly staffed from 2003 onward in the evaluation of 510-K submissions. Correct?
A I don't have an opinion on it, no. You would have to ask the device evaluation director whether she had enough people.
Q Okay. And you were not --
A He and she, actually.
Q Okay. And so from 2003 on, you have no opinion --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q From 2003 on, you have no understanding of what specifically occurred within the division that dealt with 510-K clearance.
A Oh, I -- I knew what was going on in the office of device evaluate -- evaluation as far as things that will be brought to my attention during meetings and whatever, in regard to cases.

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I knew what their staffing level was in any given year. I think I'll tell you that their staffing level increased dramatically over those years. And their usage of outside experts, fellows, panel members, became a very well-formed group of resources to evaluate premarket submissions.
Q Are you --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Do you have an opinion as to whether or not from 2003 onward, whether or not the FDA -- the portion of the FDA that would review 510-K applications or submissions, whether or not they were properly staffed or not?
A Well, I -- I think I answered you in one respect, is that I said their resources increased dramatically, and the resources they could pull in externally increased dramatically compared to when I was in device evaluation.
I -- I never -- never heard particular complaints from Dan Schultz, who was the director of device evaluation, Donna Bea-Tillman, particularly about their staffing levels being too low to do the core work that they were asked to do.
Q All right. As you sit here today, you

don't know one way or the other whether or not that portion of the FDA that dealt with 510-Ks from 2003 onward was properly staffed.

A I think you'd have to, again, ask the device evaluation director, who dealt with those issues on a day-to-day basis.

Q Right. Right. So you don't have an opinion one way or the other.

A I don't have an informed opinion --

Q Okay.

A -- because that was not my office.

Q Okay. Have you ever taken the position that the FDA, with regard to 510-Ks, takes an expansive view on what constitutes a major change in a device?

A You'll have to say that again, please.

Q Sure. Have you ever taken the position in a presentation that the FDA takes an expansive view of what constitutes a major change when determining or evaluating a 510-K application?

A Well, I guess I'd have to understand the context of that statement. Expansive? Everything that's changed has to be evaluated for significance. So in that sense, you know, the -- the front end of that deliberative process is broad.

Q Okay. So when you made that statement, expansive view of what constitutes a major change, what did you mean by that?

MR. GAGE: Objection.

A Well, there's -- in guidance descriptions of -- of various types of issues that are brought to bear when assessing a change to a device. And it covers virtually every type of change that may occur. Whether or not the change may be significant in final analysis is another story.

MR. MAZIE: Mark that.

(Ulatowski Exhibit 9 marked for identification, to be attached to the transcript.)

BY MR. MAZIE:

Q Have you ever seen -- sorry. Have you ever seen this document before, Ulatowski 9?

A I don't -- I don't think I've read this document.

Q Okay. You know what the GAO is. Right?

A Yes.

Q What is it?

A The Government Accountability Office.

Q Okay. And you were at the FDA when this report to Congress came out. Correct?

A Yes.

Q And if you look at the bottom of the second page? Last sentence says, "Furthermore" --

A The second page physically or Page 2 at the bottom?

Q Physically.

A Oh, okay.

Q The last sentence says, "Furthermore, officials said that the agency faces significant challenges fulfilling its mission to oversee the safety and effectiveness of medical products."

Do you see that?

A Yes.

Q Do you agree with that, that during your last five years or six years at the FDA, that the agency faced significant challenges fulfilling its mission to oversee the safety and effectiveness of medical products?

A I have to understand the context and derivation of that sentence.

Q Okay.

A In the office of compliance we were doing pretty well.

Q Well, why don't you read that paragraph --

A Okay.

Q -- and we can talk about it.

A Okay, I've read it.

Q All right. According to the General Accounting Office, the FDA between 1999 and 2008 faced challenges fulfilling and managing its growing medical product oversight responsibilities as a result to -- of not having enough resources. Correct?

A That's the conclusion by the GAO.

Q Did you ever agree with that, or disagree with that, that there wasn't enough resources and staffing at the FDA to fulfill and manage its oversight responsibilities of medical devices between the years '99 and 2008?

A Well, I -- I accepted the resources I had and through careful management tried to do the best I could with those resources. If I was fortunate enough to obtain more resources, great. But, nevertheless, I focused in, based upon the resources I had, using a risk-based decision process, to do the work where the work was best put to.

Q Do you agree with the General Accounting Office in its presentation to Congress that the -- between 1999 and 2008 that the FDA faced challenges in fulfilling and managing its oversight of medical devices as a result of being undermanned?

A Well, I agree with the first part. FDA is

always faced with challenges and issues that it has to react to. That's the nature of ensuring the public health.

In terms of resources, we -- we managed our resources effectively. And should additional resources come forward from Congress, through Congress appropriation, through Congressional appropriation, through the President's budget, that was fine. And we managed those resources, too.

Q Let's turn to the two, three, four -- seventh page.

A And this is Page 7 on the bottom?

Q No.

A It is not.

Q Seventh physical page. Page 1 at the bottom.

A Okay. Page 1 at the bottom. That helps.

Q It's a letter to Congress.

A Okay. I don't think I'm on the same page. Maybe we are. June 15? Okay.

Q June 19.

A Okay.

Q Last sentence of the first paragraph says, "On several occasions since then, senior FDA officials have testified before Congress and the agency issued a

report noting that the agency's funding and staffing resources do not enable it to meet its growing oversight responsibilities."

Do you see that?

A I see that sentence.

Q Okay. As of June of 2009, did you agree that for the prior ten years that the FDA did not have enough funding or staffing to enable it to meet its growing oversight of medical device manufacturers?

A If the FDA commissioner made that statement, Michael Friedman, then I'll have to rely on their statement. My own opinion is I dealt with the resources I had.

Q Well, when you say you dealt with the resources you had, that doesn't mean that you had adequate resources to oversee what you were doing.

A Well, again, a manager who thinks, when asked, Could you use ten more people, who says, No, I'm fine, you probably should have a head check on that manager.

Q Well, you also don't want to waste, either.

A Well, but more is better, believe me.

Q And again, it says -- do you know what the FDA's science board is?

A Yes.

Q Were you ever on the FDA's science board?

A No.

Q Okay. Are you aware of the fact that in November of 2007 the FDA's science board said that the agency could not fulfill its growing responsibilities because it did not have sufficient resources?

Are you aware of that?

MR. GAGE: Objection.

A You're looking at something?

Q I'm asking you if --

A Oh, I'm not aware of that, but --

Q Okay.

A -- you can direct me to something.

Q Sure. You look at the last sentence of that page, which says, "FDA's science board"?

Do you see that?

A Uh-huh.

Q Do you disagree with the FDA's science board when it reported in November of 2007 that the FDA could not fulfill its growing responsibilities because it did not have sufficient resources?

A I can't agree or disagree. I don't know what the basis for their statement is.

Q Okay. As you sit here today, you don't know whether or not those involved in evaluating

510-Ks had enough resources. Correct? We've already established that.

MR. GAGE: Objection.

A Well, what I said is, I think your question being, you know, did they have adequate resources, you'd have to ask the manager of that program.

My view from the outside in was, after working in device evaluation for many years, the size at our office doubled. The resources from externally into the office doubled or tripled; yet the 510-K numbers didn't increase. The PMA numbers didn't increase.

So the upshot is, you know, I think they were probably doing pretty well. But again, ask the device evaluation director whether she thought she had adequate resources.

Q You don't have an opinion? You have -- you're just based on -- on speculation?

MR. GAGE: Objection.

A Observations.

Q But at the end of the day, you don't know how undermanned or properly manned or overmanned they were.

A Well, if -- if in 2005 you got 600 people, and in 2002 when I left you got 300 people, well,

something good's happening there. But, you know, I'm just observing events.
Q You don't know one way or the other because you weren't working in that department or division. Correct?
A I'm -- I'm coming to a conclusion based upon the observations.
Q Without working in that department?
A Without working in the device evaluation.
Q And without speaking to the people who were in charge as to whether or not they were properly sourced.
MR. GAGE: Objection.
A That wouldn't be my decision.
Q Okay. And nevertheless, based on the General Accounting Office and their presentation to Congress, the FDA's science board reported in November of 2007 that the agency could not fulfill its growing responsibilities because it did not have sufficient resources. Correct?
A Well, if that's a statement by senior FDA staff, you know, it is what it is.
Q Okay. Let's go to Page 31. Actually, it says 31 on the bottom. It's about halfway through. First sentence: "The General Accounting

Office reported to Congress that FDA officials told them that resource constraints hindered the agency's ability to fulfill all of its medical product oversight responsibilities between Fiscal Years 2004 and 2008."
Is that correct?
A That's what it says.
Q Do you have any reason to disagree with that?
A Well, not understanding the information, who said what, I think -- I think you also have to understand -- and I'll just reflect on this from working for the agency for -- for so many years.
The agency is asked to do a lot of things. But what the agency understands within the centers, like the device center, is -- is just like when you have hypothermia. Your body concentrates its heat in the major organs.
And when there's resource issues, the resources go to the core operations. They go to device evaluation, and they go to compliance.
So, yeah, FDA people might not be going out on training excursions or might not be doing newscasts or something. Are they reducing their obligations in terms of product review and compliance? No way.

MR. MAZIE: I'm going to object and move to strike.
BY MR. MAZIE:
Q My question is simply, do you have any reason to disagree with FDA officials told the General Accounting Office that resource constraints hindered the FDA's ability to fulfill all of its medical product oversight responsibilities between 2004 and 2008?
A Well, and that's what I was answering. FDA's asked to do a lot of things. And FDA, if and when, just assuming there are resource implications, concentrates those resources in the core operations.
So someone in some area may not be doing what Congress thought they ought to be doing, in God knows what. But are they doing product reviews, are they -- are we still enforcing the law? We sure are.
MR. MAZIE: Object again and move to strike as nonresponsive.
BY MR. MAZIE:
Q I'm asking simply, do you have any reason to disagree with the following statement by senior FDA officials to Congress: That resource constraints between 2004 and 2008 hindered the FDA's ability to fulfill all of its medical product oversight

responsibilities?
MR. GAGE: Objection.
BY MR. MAZIE:
Q Do you have any reason to disagree with that statement by FDA officials to Congress?
MR. GAGE: Objection.
A Well, the term "all of its responsibilities." It -- it probably couldn't do all of the things, but it did the things that were important.
Q And those oversight responsibilities were hindered by the lack of resources. Correct?
MR. GAGE: Objection.
A All the things that FDA was asked to do, based on this statement, not understanding the basis, I'll take it as a fact, if someone said that at FDA in a senior position.
Q Okay. I'm going to ask you, in your report you have Footnote 4 on Page 8.
A Okay.
Q In that footnote you say, "I disagree with the experts' opinions as set out in my report. Some of my disagreements may not be explicitly listed in my report. I will be prepared to discuss at my deposition where I take exception to expert opinions

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and alleged facts."
Can you tell me all of your opinions and criticisms that are not contained within your expert report.
A In a -- in a broad category of -- of opinions, I enumerated a number of things, excluded specifics from my report. There's element -- there's several elements.
Expert's opinion regarding application of regulation and law that has no relevance to medical devices. Expert's opinions regarding medical aspects of which she didn't have experience or training. Expert's opinions regarding allegations of perhaps fraud, withholding documents, intentional actions to prevent FDA from being aware of certain documents.
Those sorts of things.
Q Well, those things are discussed. Those opinions are discussed in the report you issued, or reports you issued. Correct?
A Not -- not directly or specifically in -- in each case, or each instance.
Q Do you understand that under New Jersey court rules you have a requirement to give me notice of the opinions that you have so that I can discover those opinions and test those opinions?

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So my question is, you have a very lengthy report here, single spaced, and it's 74 pages long. Is there anything that's not addressed or discussed in this report and in your supplemental report that I need to be aware of?
A Well, let me answer it this way: I went through the Pence report, made comments, observations, reflections on the report. Those specific and itemized items are not in my report.
Q Okay. Do you have that handy?
A I don't have it with me. I just have the edition that was provided to counsel.
Q What do you mean, "the edition"?
A Well, the -- whatever was provided through counsel to you and others.
Q Okay. Did you actually take notes on the Pence report?
A Did I take notes on the Pence report?
Q Yeah.
A Yes, I took notes on the Pence report. I made a compilation of observations.
Q Okay. And when -- when did you do that?
A During the course of my review of the Pence report.
Q Okay. And you didn't use those comments to

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prepare any report. In other words, your report was already given. Correct?
A Uh-huh.
Q You've got to answer verbally.
MR. GAGE: You need to say yes or no.
A Oh, yes. Sorry. Well, I mean, explain that, please.
Q Well, this is what I want. You prepared your report. And then after preparing your report, at some point you reviewed the Pence report and made comments on it?
A No, I -- in the course of preparing my report, I reviewed the Pence report, made comments, observations, actually included in a -- in a prior draft, and -- and in the final draft excluded those comments from the final report.
Q Okay. So that's -- essentially what you're telling me is, the comments you made on the Pence report are -- that's a draft of this report. And you included what you felt you needed to include, and you excluded whatever you felt you needed to exclude.
A Well, I think I set it aside as -- as a record to support, you know, the statement, if necessary. If you'd like to see that, that's fine.
Q Well, this is my point. I need to know all

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of your opinions. And I have this report, and I have a very brief supplemental report.
If there's anything else that you have by way of opinions, I need to know that, whether it's in writing or verbally. So this is your opportunity.
A Well, if you provide me the Pence report, we can spend the rest of the day going through it and I'll provide my observations and opinions.
Q That's not what I'm asking you. I'm asking you -- I'm entitled to have a written opinion from you that sets forth the parameters, a summary of your opinions. I'm not going to waste my time or your time having you go through the Pence report, because you essentially have done that anyway in your 74-page single-spaced report.
I want to know, sitting here today, do you have another report, A, which you've already told me no; and, B, whether there's anything I'm missing based on this Footnote 4?
A Well, what I painted for you is, in broad stokes, are the sorts of observations, comments I had on the Pence report.
As far as specific, what I did is itemized on a page -- pages, lines where those instances occurred, my objection to certain statements.

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That's -- that constituted, at least in the prior draft.

Now, as far as what I've just told you, those in broad strokes are issues within the Pence report. If you provide me the Pence report, I'll -- I'm sure I'll have recollections of additional comments I had.

MR. MAZIE: Bill, what's your position on this document? I quite honestly don't have -- you know, I need to know from your perspective.

MR. GAGE: Well, you know, this came up somewhat with Dr. Pence as well. And I know that I've made requests for certain things that she was unable to specifically itemize at her deposition.

So I think, David, you and I probably ought to talk at a break, and let's decide how we want to -- how we want to handle this, because it goes both ways.

MR. MAZIE: I agree.

MR. GAGE: And I don't want to burn up your time with him. And I fully recognize your concern, as I had the similar concern with Dr. Pence.

So let's you and I talk and see if we can't figure out a solution.

MR. MAZIE: My proposed solution is that this -- this isn't as though we have a three-page

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report from each of them. We have massive reports. And I think that any notes that they've taken should just be kept with each of them.

I think that these more than cover all of the issues to death. And there's no reason to open doors from both sides at this point. I think that, you know -- everything's here.

MR. GAGE: Well, let me say this. And -- and don't -- I'm not trying to coach the witness. If you would prefer for him to step out, that's fine with me.

But I do know that if you were, for example, to -- I know he said there were some broad strokes, he gave you some broad strokes. And I know, for example, there are certain statements in Pence's report that he would disagree with. Okay? Like perhaps it was not of such a significant nature that it warranted putting a separate paragraph in the report.

I think probably what would -- what would be good is to ask him what he specifically recalls in terms of his disagreements with Pence's report. And then let's see what he can give you in that regard, and then you'll be able to make an evaluation of what he's giving you, and that may help inform your

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discussion and my discussion about how we handle it.

MR. MAZIE: I don't know if that's fair to me. I'm entitled to a report. He put in -- he decided to put in -- because he had her report in advance, he had for months. He put in what he put in. I don't need to waste anybody's time giving him her lengthy report to have him go line by line. And I don't think it's fair for him to say this is everything anyway.

So I think that he's followed the rules, he has two reports, he had months to prepare it, just like she did. These are their opinions.

MR. GAGE: I mean, and it's -- it's back and forth, I mean.

MR. MAZIE: But it's good for the goose is good for the gander. And I think we're both stuck with it. And I think that it's not as though they rushed the reports, and it's not as though these are short reports. They are very well thought out and very well written from both sides, so.

MR. GAGE: Well, I mean, part of it is I'd like to -- I mean, I think we would be better served by having that conversation off the record where we can talk about the specifics in terms of Pence and Ulatowski, and let's see if we can't come to some sort

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of an understanding that I could run by my client and say, Is this where we are on this issue.

MR. GRAND: The one thing the record needs to reflect, I mean, you keep saying it goes both ways. Dr. Pence doesn't have a footnote in her expert report saying, I have other opinions that I haven't disclosed in the report but which I'm prepared to discuss at my deposition.

He needs to be able to discuss them and identify them at his deposition, and under the New Jersey rules.

MR. GAGE: Well, I mean --

MR. MAZIE: It was actually before that. I'm entitled to have -- if he does have opinions that aren't in his reports, it's very clear from New Jersey case law and the court rules that he's not entitled to have those opinions. There's no element -- there's an element of surprise there, and that's what we're trying to avoid.

MR. GAGE: Right.

MR. MAZIE: All I wanted to know is, what do you have -- first of all, I am objecting to the extent he has any opinions beyond this report. Then I asked him what do you have, and he just gave me some broad statements that really don't mean much.

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MR. GAGE: Well, and -- and Jeff, in response to your point, this is -- we had this exact situation with Dr. Pence at her deposition. She had additional opinions that were not reflected in her report, which I asked her about during her deposition. And she said, I can't give them to you at the deposition, I've got to go get some additional information and look at stuff.

So, David and I have got to work through that issue. It is somewhat similar to what is on the table here with regard to Dr. Ulatowski -- or with Mr. Ulatowski. But I -- I -- but I do think -- I do think that he is -- I think he can, to the extent he can give you the specific criticisms that he -- he recalls, I'd like him to do that. And then you can proceed accordingly.

I'm not -- I'm not saying you've got to go burn up seven hours of deposition time asking him on that. But I think it would be worthwhile to ask the witness what specifically he is talking about. Beyond the broad -- you know, what are the three broad brushes, and what are the -- what are the issues underneath each of the three broad brushes, that sort of thing.

MR. MAZIE: All right. I'll spend a little

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time on this, but I -- I don't think it's fair to me to ask questions in a vacuum where I have not been given notice of what those issues are in advance and had the time to prep for that, which is what we're -- I'm entitled to.

BY MR. MAZIE:

Q So I will ask you, Mr. Ulatowski, do you have specific, specific opinions that are not addressed in your expert reports?

A What I need to do is have the Pence report in front of me. Because my specific opinions were in reference to specific pages and lines. Of course I didn't memorize everything. So I would have to do that.

Q You don't have that right now, do you?

A I don't have that list, reference, line, pages, in front of me, no.

Q That's back at your house or your office?

A Yes.

Q All right. So you're not prepared to discuss those opinions right now?

A Well, in general terms, yes.

Q Okay. Well, you just told us generally what it was.

A Yes.

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Q You disagree with her on various things, and she doesn't -- you don't think that she has certain expertise. Correct?

A Background expertise, foundation for statements in regard to various aspects of the -- of her -- regarding her opinions.

Q Okay. Can you give me specifics as to what you're talking about?

A As she courses through her discussion of background, I took issue with her interpretation of law and regulations, prohibitions, penalties, certain regulatory aspects related to MDR reporting, to -- to quality system, to aspects of FMEAs, statements made in F -- FMEAs, process. Companies should do this, should do that in terms of modifying risk-management documents, when they should do that. And her interpretation of the risk-management process.

You know, I could drill down in any number of areas. I did translate some of those points into observations or opinions in my report, but -- but not all of them.

Q All right. You can't tell me specifically which of those points aren't included in your report and give me the specific criticisms you have?

A Because they're line items, they're page

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numbers, they're -- they're quotations. So -- so, no, not in that detail.

Q Okay. All right.

What's a 510-K?

A A 510-K is a -- otherwise called a premarket notification, is a submission process made to FDA to -- at least one form of submission process made to FDA to enable a product to come to the market.

Q If a 510-K is deemed necessary but the medical device manufacturer does not submit one before marketing it, is the product legally deemed misbranded and adulterated?

MR. GAGE: Objection.

A Well, we'll have to go through that one again. And -- that's -- that's quite -- quite wordy. So let's walk through it again.

Q Sure.

A And I'll try and break it down in my mind here.

Q If a 510-K is deemed necessary but the medical device manufacturer does not submit a 510-K -- 510-K before marketing the product, is the product deemed to be misbranded and adulterated as a matter of law?

MR. GAGE: Objection.

A You've got a lot of "deemed" in there. If a 510-K is deemed necessary. In what sense?
Q By the FDA.
A Necessary informally or recommendation, a formal statement --
Q Formally.
A -- of a violation, I mean?
Q If the FDA makes a formal edict that the manufacturer needed to submit a 510-K, does that mean that the product, if it was sold before the clearance of the 510-K, was misbranded and adulterated?
MR. GAGE: Objection.
A That's where we get back to process issue. That nothing is -- nothing is automatic in this sense. The factors have to be evaluated, the appeal processes considered. You know, everything I spoke of before.
Q Let me ask you the -- when were you first retained on this case?
A Last year, earlier in the year last year.
Q 2011, 2012?
A '11.
Q Okay. First half of 2011 or second half?
A I would say first half.
Q Okay.
A I think.

Q When were you first retained on the DePuy case?
A That was under the auspices of Becker & Associates, so maybe the -- the end of last year, when I was still a 1099. It may have been earlier this year.
Q Okay. Were you retained on this case by Ethicon before you were retained on the DePuy matter?
A Yes.
Q Okay. Were you already performing -- when did you first start performing any type of regulatory consulting for any J&J entity?
A I'd have to look at my billing records. Probably last year.
Q Okay. Were you retained by a J&J entity for regulatory consulting before or after you were retained on this case as a litigation expert?
A After.
Q So the first time you were ever retained by a J&J entity was on this case?
A I believe so.
Q Okay.
A If my memory serves me well.
Q And when you performed your analysis of this case, did you do it with an open mind?

A Of course.
Q In your analysis of this case, did you have a motivation to come to a conclusion which would support Ethicon's position?
A Not initially.
When I -- when I am asked by someone to engage in a discussion of retention, I -- I almost always, if not always, tell the potential client, Look, when I get the information, the data, whatever records you're going to give me, I'm going to tell you what I think. And if what I say you don't like what I -- what you're hearing, well, I mean, that's too bad.
I lost a client last week because of that. The guy says, Well, here's the records. Well, here's what I think. Well, you would be a better expert for the plaintiff, and they fired me.
So, I mean, that's -- I just -- I try to be honest with the records.
MR. MAZIE: Okay. We have to change the tape.
VIDEO SPECIALIST: The time now is 12:36. We are going off the record. This is the end of Disk Number 2.
(Luncheon recess.)

VIDEO SPECIALIST: The time now is 1:18. We are back on the record. This is the beginning of Disk Number 3.
BY MR. MAZIE:
Q Mr. Ulatowski, what percentage of your income over the past two years has been as a result of litigation consultant -- consulting on behalf of medical device and medical product and drug manufacturers?
A Just -- I'm not precise. Could you -- could you repeat the question.
Q I'll give it to you again.
A Okay.
Q What percentage of your income over the past two years has been as a result of you acting as an expert on behalf of a pharmaceutical manufacturer being sued in court?
A Estimate, 50 percent.
Q Okay. Let me ask you, when is a medical device manufacturer required to submit a 510-K?
A The regulation specifies when those conditions exist, government regulation being 21 Code of Federal Regulations 807.
The regulation speaks to introducing a -- a new device fundamentally, making a significant change

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to an existing device.
Q And is it fair to say from your report that substantial equivalence to the predicate device is the key issue?
A That's the key factor in determination of substantial equivalence. The comparison to the predicate or predicates based upon descriptive and -- and other information provided in the 510-K.
Q And what does substantial equivalence mean?
A It means the device has the same -- is as safe and effective as the predicate device, has the same intended use as the product, has fundamentally the same technological characteristics. If it doesn't, then the data show that the differences are not substantial and there's no new issues of safety and effectiveness presented by the device.
Q If the determination leads to the conclusion that the new device is not substantially equivalent by way of intended use or by way of technical -- same technological characteristics as the predicate or prior device, is it fair to say that a 510-K is required?
A Can you repeat that question?
Q Sure. If the evidence establishes that the new device does not have the same intended use or the

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same technological characteristics or the same safety and effectiveness as the predicate or prior device, is it fair to say that a 510-K is required for the new device?
MR. GAGE: Objection.
A What I was speaking to was the process of determination of substantial equivalence by FDA. The determination of whether to submit a 510-K is fundamentally a basis of, as I said, entirely new device or a marketed device that's been significantly changed -- changed, excuse me.
So those -- those are the criteria for submission. The criteria for substantial equivalence are those factors I mentioned.
Q And the key issue in determining whether or not the manufacturer needs to submit a 510-K is whether or not the new device and the predicate device are substantially equivalent. Is that correct?
A Well, the determination of substantial equivalence is an end result of the review process. The determination of whether or not the predicate device, in what manner it compares to the device you're comparing it to, whether there's significant differences, that's a process one has to go through to assess those differences.

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Q And ultimately the manufacturer needs to make a determination as to whether or not the new device is substantially equivalent to the predicate device. Correct?
MR. GAGE: Objection.
A Well, I think that, again, the determination of substantial equivalence is a finding by FDA upon submission by the applicant. The determination of whether a change is significant, speaking about products that are modifying, is a determination made by the manufacturer.
Q All right.
A And by doing so, there is connection to the predicate in terms of the predicate's 510-K.
Q All right. What does the manufacturer have to do to determine whether or not it needs to submit a 510-K?
A It assesses each change that it has made, with the subject device, against a predicate or predicates of their choosing, in terms of various characteristics of the devices. And then the manufacturer makes a decision whether or not any one of those changes singly or in total are significant.
Q Significant how?
A Well, there's the rub. And the rub is, the

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regulation speaks of significant change. It doesn't further define what is a significant change. And so FDA, recognizing that the regulation really didn't further specify, except later in -- as directed by a determination of substantial equivalence by FDA, came out with a guidance to assist manufacturers in -- in helping to determine whether or not the changes were significant or not.
Q All right. So what -- how has the FDA provided guidance to manufacturers as to how they're to determine whether there's been a significant change in the product from the predicate product, and whether or not they need to submit a 510-K?
MR. GAGE: Objection.
A Well, the -- there's a guidance document that provides information to assist a manufacturer in making that determination. Elements of that guidance include evaluation of intended use, technological characteristics, materials, and other factors in helping the manufacturer make that determination.
Q What's the definition of same intended use?
A The same intended use, it has the same indications for use, has the same purpose to which it is claimed, fundamentally the same medical purpose.
There can be changes, differences in

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indications, but does it fundamentally perform the same function.
Q Is there any consideration of whether or not it performs the same function and is as safe and effective as the prior device?
A Well, there's a determination expectation in the documentation that's maintained by the manufacturer that they have demonstrated, through testing, design verification, design validation, that the modified device is as safe and effective as the predicate device, if that's your question.
Q Does it have to be as safe and effective?
MR. MAZIE: Strike that. Let me ask you a better question.
BY MR. MAZIE:
Q In order for there to be a determination by the manufacturer that a 510-K is not necessary, does there have to be a conclusion by the manufacturer after their testing and research that the new product is as safe and effective as the prior device?
A Well, there's a determination that the differences are not significant. And in doing so, issues of safety and effectiveness are explored. And so fundamentally the new product needs to be determined by the manufacturer to be safe and

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effective for marketing, as safe and effective, if you will.
Q Okay. So if the new product has additional new risks that the old product did not have, do they have to then submit a 510-K?
A Not necessarily.
Q Okay. When do they have to do that, and when don't they have to do it?
A As outlined in the guidance document, primarily the factors that are explored are explained therein.
Q What's your interpretation of that?
A Well, what I do even now with clients is, we walk through the changes, explore whether or not -- how they compare to the predicate; are there any particular issues presented by the differences; are those important technically, scientifically; are these the types of issues that FDA and manufacturers have looked at in prior products, factors such as those.
Q When you say that the -- in order to not have to submit a 510-K, the new product has to have the same technological characteristics as the prior product -- is that correct?
A No. Not completely. The -- there can be differences. But there needs to be an assessment of

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those differences and whether they create -- may create concerns in regard to science, engineering.
Q And what's the definition of technological characteristics?
A Oh, it can be the particular engineering design. I mean, these -- this is the broad stroke. Whether or not changes are significant is another story. But the broad stroke are -- is the form of engineering of the product, the information how it performs its function physically. Depending on the device, what kind of electrical factors, power sources, material effects. Various aspects that may come into play.
Q With regard to the Prolift, what are the technological characteristics of the Prolift?
A Well, in Prolift there's material characteristics, there's -- there's physical characteristics of the product. There is -- there's toxicological aspects related to the product, particular -- all these things may play out. There's particular shapes and designs.
I mean, these are features of the product, the features of the technology. You can get down into the weeds on the material and whatnot, but as a broad stroke.

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Q Were the -- the tools of the Prolift system considered a new technological characteristic?
A Well, I think the tools needed to be assessed, just like any other part of the product.
Q Okay.
A Were they new or not, that was for the manufacturer to assess in the process of determining significance.
Q What about the actual surgical procedure with the utilization of those tools; was that a technological characteristic that needed to be evaluated by Ethicon in determining whether a 510-K would be appropriate?
A Well, I think in a broad sense the method of usage of the product is not specifically a technological characteristic; it's a use, condition of use, process of use of the product.
Q So you think that goes to the intended use as opposed to technological characteristic?
A It can have tentacles in intended use, performance issues.
Q Okay. Fair to say that Ethicon was required to compare the Prolift to the predicate device or devices, and in doing so needed to look at how the Prolift procedure affected safety and

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effectiveness and how it compared to the predicate devices?
MR. GAGE: Objection.
A Well, it was up to the manufacturer to assess the changes in regard to the guidance document.
And in evaluating the records, I saw the process they went through, how they applied the guidance, the flow charts in the guidance, and saw that they -- they did apply the guidance in terms of all the aspects of the guidance.
Q I understand they applied the guidance; the question is whether they did it appropriately.
Let's turn to Page 24 of your report.
A Uh-huh.
Q Page 24 you have a portion of a decision tree. Correct?
A Yes.
Q All right. And that's -- that's a portion of what Ethicon was required to do to evaluate whether or not it needed to submit a 510-K to the FDA for the Prolift. Correct?
A Well, this process is actually embedded in -- and it's been updated -- embedded in the five -- in the FDA review process, actually, in determination of substantial equivalence.

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Now, many of these same features are in the guidance document on determining when a 510-K needs to be submitted or not.
Q Right. And so just so we're clear, the FDA expected that Ethicon would perform this decision tree analysis, which is shown on Page 24 of your report, in determining whether or not it needed to submit a 510-K for the Prolift. Correct?
MR. GAGE: Objection.
A It needed to perform an analysis -- well, in fact, it -- the guidance is guidance; it's not a requirement.
The only thing that's required is -- is that if a manufacturer determines significance of a change, you have to submit. The guidance attempts to further explain and explore that those simple words of significance, word of significance, and to -- and to color that as best as possible. But still it's only guidance. And it's constructive, it's useful.
And as you walk through the guidance, the manufacturer should look at the elements of the guidance and try -- and think through the guidance in regard to the flow charts.
Q Just so we're clear, the law absolutely requires that a manufacturer such as Ethicon would

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have to submit a 510-K if the Prolift represented a significant change from the Gynemesh PS product. Correct?
MR. GAGE: Objection.
A If the manufacturer, through its process of evaluation of the change, made that determination, then they should submit. If -- as the regulation points out, the manufacturer is charged with making that determination. It's not FDA's role in the first instance to do that evaluation.
And if the manufacturer makes the determination that the change is not significant, no submission is made. If they consider it significant, submission made.
Q Okay. And what -- so just so I'm clear, if Ethicon determined that the Prolift system was a significant change from Gynemesh PS, it had an obligation to, a legal obligation to file a 510-K. Correct?
MR. GAGE: Objection.
A If they followed the procedure, a logical procedure, instruct -- informed by FDA's guidance, that whatever they were doing with the new device compared to the predicate, in their analysis, was a significant change, then they should submit.

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Q And they were legally required under -- under such a scenario, if they came to the conclusion that there was significant change, they were legally required to file a 510-K. Correct?
MR. GAGE: Objection.
A The regulation says if you have a significant change as determined by the manufacturer, you submit.
Q All right. And if Ethicon internally determined that the Prolift was a significant change from any prior product, but nevertheless decided not to submit a 510-K, then it would be illegally marketing and selling the Prolift. Correct?
MR. GAGE: Objection.
A It's not my understanding they did that, based upon my review of the records.
Q Okay. Hypothetically, I want you to assume that Ethicon came to the conclusion that the Prolift was a significant change from prior products. Under that scenario, if they did not obtain a 510-K but nevertheless sold and marketed the Prolift, they would be illegally marketing the product. Correct?
MR. GAGE: Objection.
A Well, I would say that who's the responsible party in the company to render that

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decision? Who's the signatory, the person that is responsible for making that determination? What did they do, what process did they follow, what conclusions did they reach and decisions made.

So based upon my review of the records, they followed the process as outlined in the guidance document.

MR. MAZIE: Objection.

A They made a decision, it was not significant.

MR. MAZIE: Objection. Move to strike as nonresponsive.

BY MR. MAZIE:

Q I'm asking it -- please listen to my question.

My question is, I want you to assume that the powers that be, people at Ethicon, came to the conclusion that the Prolift was a significant change from any prior products. If that were the case, and Ethicon did not submit a 510-K but nevertheless sold the Prolift, do you agree with me that the Prolift would be illegally sold?

MR. GAGE: Objection.

BY MR. MAZIE:

Q Under that scenario?

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A Well, two aspects.

One is, in restating the question, you added the -- "the powers that be," implying the appropriate people within the company responsible for making that decision, that determination, made the determination that there was a significant change, compared to the predicate or predicates. I mean, that's how you modified the second time around.

And -- and choose -- chose not to submit. Well, then that would kick in at the back end, FDA's process of determining whether, in fact, there was a violation.

Q Let me ask you this: Who -- who should -- based -- you've reviewed the -- reams of materials, depositions, and documents in this case in coming to your conclusions. Correct?

A Yes.

Q Okay.

A Uh-huh.

Q And you reviewed anything that you thought was pertinent in any way so that you could arrive at the appropriate and honest conclusions in this case. Correct?

A Yes.

Q Okay. Do you know who Dr. Arnaud is?

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A The name is familiar to me, yes. I -- I don't recall his exact -- the exact title.

Q He's one of the French doctors who invented the --

A Yes, that's right.

Q -- the Prolift procedure.

A Right.

Q Correct?

MR. GAGE: Objection.

A I believe so.

Q Okay. If Dr. Arnaud --

A Prolift, I mean, but used a certain similar design and -- yes.

Q Okay. And if Dr. Arnaud had come to the conclusion that the Prolift was a significant change from any prior product, would you believe that that would be binding on the company?

MR. GAGE: Objection.

A I -- short answer, no. Longer answer is, he's -- he's probably not in the chain of decision-making to render the final company decision on that matter.

And during the course of evaluation, assessment of a product, lots of things are said during the course of design reviews and construction.

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What ultimately is the case is, and it's usually the responsibility of the regulatory people in the organization, to consider the facts, to apply in this case the guidance by FDA, and to render a decision.

Q Well, who are the regulatory people in this case?

A Well, Catherine Beath is -- is at the top. There were other people involved in the Project D'Art documentation and discussions.

Q And are you aware of the fact that Catherine Beath deferred to the people in medical affairs as to whether or not the Prolift was a significant change from Gynemesh or any other device?

MR. GAGE: Objection.

A Well, regulatory is responsible for making the decision. They may be informed by others. I'm just speaking in general as I know organizations to be constructed.

Q Mr. Ulatowski, do you know whether or not Ms. Beath, Catherine Beath, deferred to people in medical affairs as to whether or not the Prolift device was a significant change? Do you know that one way or the other?

MR. GAGE: Objection.

A I know that she did -- she understood her

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limitations in regard to medical knowledge and experience. So on certain labeling issues, medical issues, she did defer to the medical staff.

But upon reaching their recommendations input, I think the burden ultimately -- and I'll speak in general as I understand medical device companies -- is the regulatory group makes a regulatory decision in terms of filing.

Q Who made the decision at Ethicon that the Prolift was not a significant change and that, therefore, no 510-K was necessary?

A I'll refer to my report.

MR. GAGE: Objection.

BY MR. MAZIE:

Q Sure.

A I'll have to look at the table of contents. I'm probably looking right over.

Sean O'Bryan was in the mix, probably worked for Catherine Beath. Bryan Lisa also in regulatory. I mean, those are names that just -- not spending all day on this. And Catherine Beath is at the top of the org chart there in regard to --

Q As you sit here today after creating the 74-page, single-spaced report after reviewing reams of documents after earning tens of thousands of dollars,

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can you tell this jury who at Ethicon made the final decision that the Prolift was not a significant change, and that, therefore, no 510-K was necessary to be filed with the FDA?

MR. GAGE: Objection. Objection.

A Well, I'll read further.

I think it was in the regulatory strategies that the Project D'Art, 2004, it looks like a critical point in time.

Q You're not answering my question.

I'm asking you who; what person or persons made the decision at Ethicon that the Prolift was not a significant change from any other product, and that, therefore, no 510-K need be filed with the FDA.

Who made that decision?

MR. GAGE: Objection.

A That decision was ultimately regulatory. The head of regulatory is Catherine Beath. She was ultimately responsible for that decision.

Q So if Catherine Beef --

MR. MAZIE: Strike that.

BY MR. MAZIE:

Q If Catherine Beath came to the conclusion that there was a significant change in the -- from the -- between the Prolift and any other device or

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product, then a 510-K should have been filed with the FDA. Correct?

A If it was documented based upon a review of the FDA guidance -- guidance document, that the Prolift presented a significant change, after evaluating the flow charts, then there was an expectation there was a significant change according to regulations and there should be a submission.

Q All right. And if Catherine Beath came to the conclusion that there was significant change by -- by virtue of the Prolift as compared to other products, and nevertheless the product, the Prolift product, was sold and marketed without a 510-K, then that product, the Prolift, would be illegally marketed. Correct?

MR. GAGE: Objection.

A If she -- well, first of all, I'll have to -- assuming -- I'll have to take a look further. Assuming she was there at the time of the launch of the Prolift, and she was the responsible party at the time, being the regulatory head, or if she was not there at the time, whoever was the regulatory chief signed off on the significance, the end result being significance, there would be an expectation that there would be a submission.

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Q And if there was no submission but the Prolift was sold, it would be illegally marketed and sold. Correct?

MR. GAGE: Objection.

A Well, that determination is a determination, getting back to misbranding and adulteration. And I've talked about the process of FDA evaluating the evidence in order to render a finding that there's a violation.

Q Well, we've just talked about. The law absolutely requires that there's a significant change that a product can't be sold unless a five -- there is 510-K clearance. Correct?

MR. GAGE: Objection.

A There would be an expectation of submission. As far as a finding of misbranding or adulteration, that's another process.

Q Is it fair to say that the law requires that if there's a significant change, that a 510-K be cleared by the FDA before the product is sold. Correct?

A If there is a significant change to a marketed product, there is -- regulation says submit.

Q And if you don't submit but you sell it, you're selling illegally. Correct?

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MR. GAGE: Objection.
A Again, that's a finding by FDA based upon evidence and a charge.
Q You think that only FDA can make that determination.
MR. GAGE: Objection.
A Well, I -- I imagine people can in a cavalier way throw those terms out. But ultimately it's -- it's a finding based upon evaluation of evidence, just like somebody shoots somebody outside, you don't immediately charge them with murder. You evaluate the evidence, the facts of the issue.
Q Mr. Ulatowski, if Catherine Beath testified that she relied on medical affairs and other medical experts in arriving at her conclusions, would you disagree with that testimony?
A If in fact that --
MR. GAGE: Objection.
THE WITNESS: Excuse me.
MR. MAZIE: Let me withdraw the question.
BY MR. MAZIE:
Q Do you know whether or not Catherine Beath testified that she relied on medical affairs and the medical experts in arriving at her decision and her group's decision as to whether or not there was a

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significant change?
A Well, there was certainly input from medical folks about the fundamental basis, support -- supporting evidence, data, information, in order to move forward to launch the product. But, you know, relying on that, reliance is one thing; making a decision is another.
Q Who did the people in regulatory, including but not limited to Catherine Beath, rely on in determining medically whether or not the Prolift was a significant change from another product?
A Well, first of all, I don't think that Catherine Beath relied solely upon medical affairs in regard to significance of certain aspects. The medical affairs people, for example, weren't the engineers. Medical affairs people didn't necessarily do the engineering analysis.
So regulatory will -- in this case Catherine Beath, would consider the input from the various staff members, including medical affairs, and render a decision.
Q Who specifically did Catherine Beath rely on in arriving at the decision that there was no significant change between the Prolift and any other product, including but not limited to Gynemesh?

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A Well, the decision tree in the -- the marketing strategies documented in every variation of the Project D'Art strategies, documented the -- the logic, the decision-making process, in order to determine whether or not a submission needed to be -- needed to be made. And I mentioned a couple of folks who contributed to those -- those strategies. And in those strategies, also, is input from other folks.
Q Who were the people?
A Well, you may need to pull out the strategies.
I do have reference to opinions by medical staff. But the Project D'Art strategies, I'd have to go to the source documents, because I don't -- haven't cut and pasted those strategy documents into my report.
Q Was Dr. Arnaud part of that evaluation as to whether or not there was a significant change in the Prolift as compared to other predicate devices?
A I'd have to look at the source documents and the strategy documents to see who is mentioned participated. What I have is the regulatory staff's conclusions, opinions, regarding the outcome of that assessment.
Q Have you seen the source documents?

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A Oh, sure.
(Ulatowski Exhibits 10 through 14 marked for identification, to be attached to the transcript.)
BY MR. MAZIE:
Q All right. I'm going to show you -- let me put these in order.
A There's a number of them, various dates.
Q Just hold on.
I'm going to show you what's been marked as Ulatowski 12. Is that one of the documents you were referring to?
A No, I didn't pick it up at this point. The earliest Project D'Art memo I have, at least from what I can see, is from September of 20 -- 2003. I remember this.
Q You remember this document? You've seen this?
A I think I -- I remember this document. Let me just look at it.
I think I recall this document. But I didn't reference it. When I --
Q What is this document?
A -- when I picked up the train of decision-making.
Q What is this document?

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A It looks like a presentation.
Q This is one of the documents that makes up the regulatory strategy. Correct?
A Well, it's a document that's in a chain of events regarding the design history of the product.
Q If you look at Page 3 of this document, it talks about a working group of highly skilled and innovated pelvic surgeons is initiated, and it lists Dr. Arnaud as one of them. Correct?
A Yes. Uh-huh.
Q Dr. Arnaud is one of the people that led the development of the Prolift. Correct?
A The -- the type of product, procedure.
Q Is that correct?
A The type of product and procedure.
Q What do you mean by that?
A Yes.
Q I mean, what do you mean by that, Mr. Ulatowski?
A Well, evaluating the -- the particular vaginal approach to implantation of this type of mesh procedure, mesh into the -- in the pelvic space.
Q What was Dr. Arnaud's involvement with regard to the development of the Prolift?
A Well, he certainly informed Ethicon in

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regard to performance of the product by the approach, vaginal approach, using similar, very similar types of designs. So instructive all the way through the process, a source of information, probably.
Q Dr. Arnaud was a representative of Ethicon. Correct?
A I don't recall his exact title. I could probably -- I probably have it in my report, but I don't recall his exact title.
Q But you know that he was -- he was an employee of Ethicon. Correct?
A I think -- I think so.
Q Okay. And you know that Dr. Arnaud was one of the people that was involved from the beginning in developing the Prolift until launch. Correct?
A I recall his name early on, yes.
Q And through -- through launch. Correct?
A He was -- he may have been there. I don't recall specifically, but ...
Q And Dr. Arnaud is one of the people that the people in regulatory ended up asking questions of and relying on in determining whether or not there were significant changes and what risks were associated with this new Prolift procedure. Correct?
MR. GAGE: Objection.

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A Well, as any employee, you have input into a process. So, you know, I would expect that.
Q Are you aware of the fact that initially, at least, Ethicon came to the conclusion that 510-K clearance would be required?
MR. GAGE: Objection.
A I think I've seen a document along the way, whether it's in here or elsewhere.
Q Okay. Let's go to Page --
A Where there's a statement to that effect.
Q Let's go to Page 10.
Under the Key Assumptions for the Prolift, it was assumed that the Prolift would require 510-K approval -- sorry, clearance. Correct?
MR. GAGE: Objection.
A What it states here is regulatory clearance, 510-K.
Q Right. So as of June of 2003, people in regulatory at Ethicon were of the belief that they needed 510-K clearance for the Prolift before marketing it. Correct?
MR. GAGE: Objection.
A Well, people identified here had that belief at least.
Q And the people that were identified here

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were Reinhard Juraschek, Scott Ciarrocca, Bob Roda, and Celine Buard. Correct?
A Yes. Uh-huh.
Q If you look at Page 13?
A Uh-huh.
Q Never mind that page. That's not the page I wanted.
Okay. Go to Page 17, I'm sorry.
A Okay.
Q They have a regulatory strategy as of June of 2003 that in the U.S. they're going to submit a 510-K to the FDA to the Prolift. Correct?
A It says U.S. --
MR. GAGE: Objection.
A -- FDA with 510-K.
Q Next page, 18. They have the project schedule. And included in that project schedule is the fact that they need to submit a 510-K for the Prolift to the FDA. Correct?
MR. GAGE: Objection.
A Well, what's stated is U.S. regulatory approval, U.S. 510-K, 510-K, FDA review of 510-K.
Q Right. So clearly, according to this document, as of June of 2003, Ethicon -- the people in regulatory at Ethicon were of the opinion, based on

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the project schedule, that they needed to submit a 510-K to the FDA for the Prolift. Correct?
MR. GAGE: Objection.
A From what I see, some people believed that to be the case.
Q Okay.
A But, of course, this is in --
Q Excuse me?
A This is in 2003. I've got lots of clients who approach me and say, Well, we're going to need a 510-K. And I instruct them it's not the case.
MR. MAZIE: Objection. Move to strike as nonresponsive -- nonresponsive.
BY MR. MAZIE:
Q Let's go back again.
As of June of 2003, the people who prepared this regulatory document, meaning Mr. Juraschek, Mr. Ciarrocca, Mr. Roda, Ms. Buard, people at regulatory at Ethicon, were of the belief that they needed to submit a 510-K for the Prolift. Correct?
MR. GAGE: Objection.
A It's stated as is. But that's not where you start out; it's where you end up in the analysis.
MR. MAZIE: I again object and move to strike.

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BY MR. MAZIE:
Q And I'll ask you the question again.
As of June of 2003, people in regulatory at Ethicon prepared documents that included a project schedule that required them to submit a 510-K for the Prolift before selling it. Correct?
MR. GAGE: Objection.
A Well, people who constructed these slides have this in their timelines. I mean, that's what I see.
Q And one of those people was Scott Ciarrocca. Correct?
A That's right.
Q Do you know who Scott Ciarrocca is?
A I remember the name. I don't recall his title.
Q All right. Put that away.
A If -- if I can add to how that --
Q There's no pending question.
Let me show you what's been marked as Ulatowski 14. Have you seen this document before?
A I believe so.
Q What's a -- what's this document?
MR. GAGE: David, do you have another copy of this?

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MR. MAZIE: Sure.
A Well, as part of a design review process, validation is one element of that design process.
Q If the Prolift was a completely new procedure from what doctors were used to doing or performing, that would constitute a significant change. Correct?
A Well, I probably would refer to medical expertise on that to render a conclusion whether that was a fact or not.
Q I'm asking you this question. I want you to assume that doctors as a whole --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q I want you to assume that doctors would generally believe this procedure, the Prolift procedure, to be a wholly new procedure. If that were the case, that would render the Prolift a significant change from any prior product. Correct?
MR. GAGE: Objection.
A I don't -- I don't know. What doctors? What opinions? I'd have to have more information there, I think, to understand the parameters of that.
Q Okay. Let's look at this document. Let's look on Page 6 of 15.

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Are you there?
A On what page?
Q Six.
A Oh, 6. Okay.
Q Are you there?
A Okay. Yeah.
Q This is a -- this is the design validation report for the Prolift. Correct?
A Yes.
Q This is one of the required regulatory pathways. Correct?
A Design validation is -- is a requirement to the quality system, yes.
Q And this is dated February 7, 2005. Correct?
A Yes.
Q This is weeks before the launch of the Prolift. Correct?
A I believe so.
Q If you look at the last sentence in the response box, it says, "Clearly, for most physicians the Prolift procedure will be a deviation from what they are currently doing."
Do you see that?
A I see that.

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Q Okay. So as of February 7, 2005, a mere few weeks before the launch of the Prolift, the people at regulatory at Ethicon were of the opinion that for most physicians, the Prolift procedure will be a deviation from what they are currently doing.
Correct?
MR. GAGE: Objection.
A I'll have to see whose responses these are again, just to refresh my memory, who actually made those responses.
I mean, the only signatory on this document is from marketing. Let me look further.
Well, I don't know who made the comment, that would be helpful.
Q I'm asking you to assume -- first of all, do you know who Giselle Bonet is?
A Giselle Bonet?
Q Yeah.
A She's indicated as product director, Gynecare, marketing.
Q Okay. And she's signing off on this design validation report for the Gynecare Prolift system a few weeks before its launch. Correct?
A Yes.
Q And according to this design validation

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report, most physicians doing the Prolift procedure will deem this as a complete deviation from what they're currently doing. Correct?
MR. GAGE: Objection.
A That's a response comment.
Q Correct?
A That's what it states.
MR. GAGE: Objection.
BY MR. MAZIE:
Q And again, if in fact -- I want you to assume, I want you to assume for this hypothetical that the Prolift procedure is completely, is a completely new procedure and completely different from what doctors were used to doing. If that were the case, that would be a significant change, requiring a 510-K. Correct?
MR. GAGE: Objection.
A No, I can't conclude that.
Q Why not?
A I think, first of all, what I would do is, I'd solicit the input of -- of medical experts to give me some input on that, to assess that.
I'm not going -- I'm not a urogynecologist, I'm not going to assess on my own the significance of a medical procedure versus another.

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So that's kind of the long and short of it.
Q Okay. So you're not a medical expert. But you don't know who the people at regulatory at Ethicon consulted with in arriving at the conclusion that for most physicians the Prolift procedure is a deviation from what they're currently doing. Correct?
MR. GAGE: Objection.
A Well, all I see is what's stated here. I don't know who wrote it, I don't know based on what -- you know, what their assessment was, basis for assessment.
Q All right. Let me ask you this: I want you to assume hypothetically that after speaking to all the medical experts, and doing their analysis, that the people at Ethicon came to the conclusion that the Prolift procedure for most physicians is a deviation from what they're currently doing. I want you to assume that's the case, that's the conclusion they reached.
If that were true, that would constitute a significant change, which would require a 510-K for the Prolift. Correct?
MR. GAGE: Objection.
A I'd say it would be an issue that would have to be assessed clinically. I'm -- I'm just

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thinking back in other situations where I've been presented the same sort of situation. I -- I haven't made that determination independently in -- in past -- past times.
Q So right now, sitting before this jury on video, you can't reach a conclusion, even if I tell you to assume that the people at regulatory affairs, in their -- in their design validation report, came to the conclusion after speaking to medical experts that most physicians performing the Prolift procedure would find it to be a deviation from what they're currently doing, you can't come to the conclusion one way or the other as to whether or not that represents a significant change which requires a 510-K.
Is that what you're telling this jury?
MR. GAGE: Objection.
A Well, a deviation, how significant is a deviation? How different is it from other procedures? I'd have to get some input on that to understand the -- the importance of that.
Q And, again, you'd have to get input, if you were sitting in their shoes, from the medical experts?
A Well, the statement is, it would be a deviation. Okay. It's a deviation. Well, lots of changed products, there's some change in process or

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procedure using the product, but it doesn't require a 510-K.
So, you know, I'll -- what have people been doing, how does this deviate from that.
Q Who -- who would you have to --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Who should they speak to --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Do you know who the -- who was on their medical affairs as a consultant, or within the company?
A Robinson, Hinoul, others.
Q Okay. Dr. Vincent Lucente?
A There was a -- there was a design group, a medical group. I read their depositions. So that was separate from the medical affairs staff --
Q Fair to say that --
A -- somewhat.
Q -- two of the primary people who were -- who were leading the inquiry and evaluation concerning the Prolift were Dr. Vincent Lucente in the United States and Dr. Axel Arnaud in France?
A Those were people involved --

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Q Okay.
A -- in the process.
Q Dr. Lucente was involved in the American TVM study, and Dr. Arnaud was involved in the French TVM study. Correct?
A Yes.
Q And both studies were done to evaluate whether or not the Prolift was safe and effective. Correct?
MR. GAGE: Objection.
A That -- to evaluate the procedure, to evaluate the vaginal approach in pelvic order, pelvic prolapse, yes.
Q Okay. And both TVMs, the French and the U.S., led by Dr. Arnaud and Dr. Lucente, was to determine the safety and effectiveness of the Prolift procedure.
MR. GAGE: Objection.
A Yes, it was useful and referred to by Ethicon.
Q And they were also, both TVM studies, both in France and in the U.S. by Dr. Arnaud and Dr. Lucente amongst others, was to determine whether or not the procedure itself was a significant change. Correct?

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MR. GAGE: Objection.
BY MR. MAZIE:
Q From prior procedures.
A Well --
MR. GAGE: Objection.
A -- I mean, they -- I'm not a urogynecologist, so you're going to test the limits of my expertise here.
But, you know, they provided input. There were other medical staff in the company that also provided medical input, knowing full well what those individuals thought. Charlotte Owens, Robinson, Hinoul. They knew all that same information, and they moved forward on the product, saying, no, these are -- people are used to operating in this space, this is nothing unusual.
So, you know, there's opinions, there's opinions.
Q People make mistakes, don't they?
A Sure.
Q Okay. And sometimes people look the other way even though they know it's wrong. Correct?
MR. GAGE: Objection.
A Well, I'm sure that occurs.
Q You've seen that. You've -- as -- sitting

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in your chair as an FDA regulator, you've seen many companies do the wrong thing.
MR. GAGE: Objection.
BY MR. MAZIE:
Q Correct?
MR. GAGE: Objection.
A From time to time companies will not comply.
Q And sometimes it's by mistake. Correct?
A Yes.
Q And sometimes it's intentional. Correct?
A Unfortunately, yes.
Q Here the brochure for the Prolift said that the product, the Prolift, is revolutionary. Correct?
A I think that term was used at one point in time.
Q The word "revolutionary" means significantly new, does it not?
MR. GAGE: Objection.
A Well, I've -- I reviewed marketing and advertising and labeling for many years. And companies will -- the marketing people will say things that have no real bearing on the evaluation of significance and -- and determination of equivalence. I mean, these are marketing people who will try and --

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you're in a bit of a contradiction here with 510-Ks. The contradiction is, the 510-K process you're trying to establish equivalence. And the marketing people are trying to get some spread of product differentiation with their customers.

Q Let me ask you this: If the Prolift was truly revolutionary, that would constitute a significant change for which a 510-K would be required before Ethicon sold the product. Correct?

MR. GAGE: Objection.

A I'd have to see the wherewithal under -- supporting the term "revolutionary." And I think the company did look at those elements and made a decision that it wasn't.

MR. MAZIE: Objection. Move to strike.

A That it was substantially -- well, was not a significant change.

MR. MAZIE: Objection. Move to strike as nonresponsive.

BY MR. MAZIE:

Q I'm asking you to tell this jury -- first let me ask you it this way: I'm asking you to assume that the Prolift procedure was truly revolutionary, meaning a completely new procedure that doctors had not done before.

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If that's the fact, if you accept that as a fact, that it's a revolutionary new procedure, do you agree with me that constitutes a significant change which would have required Ethicon to have filed and got clearance for a 510-K before selling the Prolift?

MR. GAGE: Objection.

A And I can't agree with that.

Q Why not?

A Well, I -- I harken back to my experience. And FDA's determined in conversation with companies some -- some things not significant or have not -- even though somebody might think they're revolutionary or a big deal, FDA's not expected a 510-K or found a -- or has found a 510-K equivalent, even though the change might be a big deal.

MR. MAZIE: Objection. Move to strike.

BY MR. MAZIE:

Q You have to listen to my questions.

A Right.

Q My question is, I want you to assume, I want you to assume that the Prolift was a revolutionary, new procedure. I want you to assume that as fact.

If that were the case, that would constitute a significant change which would have

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required Ethicon to have submitted a 510-K and received clearance from the FDA before selling the product. Correct?

MR. GAGE: Objection.

BY MR. MAZIE:

Q Under that hypothetical.

MR. GAGE: Objection.

A Well, the hypothetical is -- is formed in my mind with an expectation what you -- what one considers to be revolutionary, which every person has a different idea of what's revolutionary. Marketing people sometimes call minor things revolutionary just to get market spread.

So I don't take revolutionary -- FDA doesn't consider the word "revolutionary." It looks at the data, it looks at the changes, the technology, and renders its opinion. The regulations expect the companies to take a look at those changes, compare it to the predicate, and render a decision on whether these things are significant.

Q Well, is it appropriate for Ethicon to say that its product, the Prolift, is revolutionary, if that's not true?

A Well, I guess what I'm saying is, revolutionary is in the eye of the beholder. And how

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one considers, you know, what is revolutionary.

Q I'm asking you a question. Is it appropriate or was it appropriate for Ethicon to state in its materials that the Prolift is a revolutionary -- revolutionary procedure, if that weren't true? Would that be appropriate?

MR. GAGE: Objection.

A By whatever definition they used for revolutionary. Didn't necessarily mean it required submission.

Q What's your definition, what was your definition at the FDA as to what revolutionary meant?

A Well, I think that that's really a case-by-case situation or a product-type-by-product-type definition, or application.

FDA was, for example, at one time considering scalpels in the same ballpark as lasers. I mean, so it's a -- you know, what is revolutionary? Does it dramatically change medical practice? I -- I don't know. I -- I just didn't rely upon terms revolutionary, because they're ill defined, they're subjective almost.

Q You don't know what the term "revolutionary" means?

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A Well, there's probably a dictionary definition of some remarkably huge change or something, but that's not -- in marketing literature that's -- I mean, that's not tightly held to the definition, probably.

Q Mr. Ulatowski, what is your understanding of what revolutionary means?

A Well, I guess a common definition, just as I construct one here, would be a -- a substantial change that -- that has significant impact on whatever the revolution is.

So it -- I mean, you know, you asked me a term. I answer with some other terms that probably require a definition. But again, FDA -- and even now I don't -- I don't put much stock in the term "revolutionary." I don't think -- I don't recall an instance where that changed my mind about a product one way or the other.

I looked at the data and information.

Q So it's okay if a manufacturer, while you were at the FDA, it was okay if a manufacturer said that their product was revolutionary or there was a revolutionary new procedure, even if that weren't the case?

A I don't recall ever taking an action

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against someone who made that -- who stated the term "revolutionary." I guess I would have to consider its importance, how -- its impact. I don't know exactly how I would approach it.

Q Let me ask you, if a manufacturer was of the opinion that there -- that the Prolift --

MR. MAZIE: Strike that.

BY MR. MAZIE:

Q If Ethicon was of the opinion that the Prolift is a novel surgical protocol and that there needed to be special skill or training to perform the procedure, would that be a significant change requiring a 510-K?

A Well, I know that there were statements made by people along the way, be it novel, revolutionary, whatever. What I was interested in was, how did Ethicon make their decision on significance? What -- what decision did they make, what did -- what did they support it with? So what was the process they went through.

There's lots of things that -- in there that, for example, in the Pence report that, well, you know, lots of things are said when in a company. It's what -- when you boil it down to what's the regulatory process to determine significance.

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MR. MAZIE: I object and move to strike as completely nonresponsive.

BY MR. MAZIE:

Q Are you hearing my questions?

MR. GAGE: Objection.

A I am.

Q You seem to be -- I ask you a question, and you seem to answer something completely different. I don't -- I don't understand. You understand you're being videotaped and you're under oath. Right?

MR. GAGE: Objection.

A I understand.

Q All right. I'm going to ask you again. If medical affairs --

MR. MAZIE: Strike that.

BY MR. MAZIE:

Q If Piet Hinoul -- let's do it this way: If Piet Hinoul relied on medical affairs and his medical experts told him this was a completely new procedure, would that constitute a significant change for which a 510-K would be necessary and cleared by the FDA before Ethicon could legally sell the product?

MR. GAGE: Objection.

A That would have to be assessed according to the guidance, decision made, move on.

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Q What does that mean?

A That's what the -- well, Piet Hinoul says it's significant. I mean, that's -- that's an element. That's considered. You know, the -- lots of things are said during the course of design and review of a product. When push comes to shove, what's -- who's the responsible party, what decision did they make, and on what basis.

Q Again, you don't know who the responsible is as you sit here today. Correct?

A No, I think I --

MR. GAGE: Objection.

A I think I proffered Catherine Beath as the most senior regulatory person.

Q Not Piet Hinoul?

A Not Piet Hinoul.

Q Okay.

MR. MAZIE: Mark this.

(Ulatowski Exhibit 15 marked for identification, to be attached to the transcript.)

BY MR. MAZIE:

Q Have you ever seen this document before, this e-mail?

A Hang on just a second here.

MS. KABBASH: I'm sorry, what's the number?

The exhibit number?
THE WITNESS: Fifteen.
MS. KABBASH: Thank you.
THE WITNESS: Is that right? Yeah.
A Okay. Let me take a look at this.
I've seen this.
Q You have?
A I've seen this in Pence's report.
Q Okay.
A Cut and paste.
Q And again, the legal determination of whether a 510-K is necessary is if there's a significant difference or a substantial change; which is it?
MR. GAGE: Objection.
A A significant change.
Q Significant change.
A Right.
Q Okay. I want to look at this document -- first of all, do you know who Steve Bell is?
A I see his -- his title here, director of marketing, Europe.
Q For Gynecare?
A Gynecare.
Q Okay. And he said that, "As agreed, the

top ten key learnings from the first TVM training course in Lilly," do you see that?
A Yes.
Q And if you look down at four -- the third bullet, it says, "The TVM" -- referring to the Prolift procedure -- "represents a major" -- the words are all capitalized -- "mind shift on several key aspects of prolapse surgery that may require a greater shift in thinking."
Do you see that?
A Yes.
Q He was of the opinion that the -- one of the key learnings from the training course in Lilly for the Prolift was that there's a major mind shift on several key aspects of the Prolift surgery. Correct?
A Well, he says what you first said. I mean, you don't need to paraphrase it.
Q In the fourth bullet he states, "The dissection of posterior compartment for this procedure is significantly different" -- and I want you to focus on significantly different -- "to that of either standard sacrospinous fixation procedures, (Richter) or even posterior IVS."
Do you see that?
A Yes.

Q Okay. So one of the key learnings from the French TVM was that the Prolift procedure is significantly different from any other prolapse surgery. Correct?
MR. GAGE: Objection.
A Well, it is as stated here, as you've read it.
Q Do you understand that to be the case, based on this internal e-mail, that one of the key learnings from the TVM training course in Lilly, France, was that the Prolift procedure is significantly different than other Prolift -- prolapse repair surgeries?
MR. GAGE: Objection.
A It doesn't quite say that, but -- it says significantly different to that for either standard sacrospinous fixation procedures or even for posterior IVS.
It's one of the characterizations by Steve Bell of the key findings.
Q Okay.
A Key learnings.
Q And people that are cc'd on this are Scott Ciarrocca, Giselle Bonet, Ophelie Berthier, K. Munchel -- I'm sorry, Kendra Munchel, and Kevin Mahar,

all of regulatory affairs or medical affairs at Ethicon. Correct?
MR. GAGE: Objection.
A I recall some of the names.
Q Okay. Well, you knew who Scott Ciarrocca was?
A Yeah. I forget his title. But, yeah, I -- he's in a number of documents.
Q Okay. And so these various individuals in regulatory and medical affairs at Ethicon were in agreement that the Prolift procedure was significantly different to that of other prolapse repair surgeries.
Correct?
MR. GAGE: Objection.
A Well, I don't know if you can conclude that. I mean, it's a e-mail from Steve Bell to -- to people. I don't know what their beliefs were.
Q All right. Let's assume these people, Scott Ciarrocca and some of these other people, agreed that the Prolift surgery was a significant difference in procedure from any of the other existing prolapse repair surgeries. Do you agree with me that a 510-K would have been required before they could sell the Prolift?
MR. GAGE: Objection.

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A I don't think I can really answer that. I think you're testing the limits of my expertise here.
What I would typically do would be to solicit the assessment, opinion by -- by a urogynecologist, probably.
Q Okay. Such as Dr. Lucente or Dr. Arnaud. Correct?
MR. GAGE: Objection.
BY MR. MAZIE:
Q Two people that were leading these TVM studies in France and the United States. Correct?
A Well, and there were other medical staff. So, I mean, these are statements made, but my opinion was that they followed the right procedure.
MR. MAZIE: Move to strike as unresponsive.
BY MR. MAZIE:
Q That's not what I asked you.
I asked you whether or not if the people in regulatory affairs believed that the -- that one of the top ten learnings from the TVM training was that the Prolift procedure was significantly different from other types of prolapse repair, that that would require them to have a 510-K before selling the Prolift. Correct?
MR. GAGE: Objection.

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A I -- I can't conclude that. I would require further input. And it wasn't the nature of my opinion in regard to the -- the topic which you're discussing, which is significance of the change, and the decision made by the company.
Q That was not part of your -- your opinion.
A It was.
Q Okay. My question to you is, you would have to -- and I think you said this earlier. You would have to hear from urogynecologists who were familiar with the procedure. Correct?
A I would solicit input. I wouldn't -- I'd select that input based upon my requirements, and then maybe formulate an opinion if I could still make an opinion.
Q Okay.
MR. MAZIE: Let's mark this.
(Ulatowski Exhibit 16 marked for identification, to be attached to the transcript.)
BY MR. MAZIE:
Q Dr. Arnaud is one of the creators of the Prolift procedure and one of the people who ran the TVM study in France. Correct?
MR. GAGE: Objection.
A Yes.

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Q And have you seen his deposition, his sworn testimony? Because it's not listed on your supplement anywhere.
A I don't recall Arnaud's deposition. I have to look at my reliance list.
Q Why don't you look on your reliance list, because I don't see it.
A I don't see it on Page 80, and the rest are I think individual documents. So I think the short answer is I don't think I saw his deposition.
Q You rendered an opinion in this case without reviewing the sworn testimony of Dr. Axel Arnaud? Is that what you're telling this jury?
MR. GAGE: Objection.
A I didn't review the deposition. It doesn't mean I couldn't render the opinion.
Q Well, you knew that Dr. Arnaud was deposed in this case. Correct?
MR. GAGE: Objection.
A I don't know if I knew that or not. I don't recall.
Q If you knew -- okay. If you knew that Dr. Arnaud, who's one of the inventors of the Prolift procedure and one of the people who led the TVM study, had been deposed, you would have wanted to read that

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before rendering your opinions. Correct?
MR. GAGE: Objection.
A I don't know. My -- my opinion is one of process. I'm not a urogynecologist. I'm not going to sit here and opine on medical procedures, importance, differences. That's not my bag. My bag is the regulatory process that they used, the basis, the foundation for the decision in a regulatory sense, and the outcome of that.
Q So it wouldn't matter to you -- you're telling this jury that it would not matter to you if Dr. Arnaud, who is one of the people who was shepherding the Prolift procedure from its infancy to the time it was marketed or through the time it was marketed, what his opinions were?
MR. GAGE: Objection.
A What I did find in depositions --
Q Please answer my question.
A I -- I don't know.
Q You don't know whether you would be interested in what Dr. Arnaud had to say about the product?
A Until I -- if I read it and there was nothing substantial in terms of the regulatory decision process.

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Q Well, you didn't read Dr. Arnaud's deposition?
A No, I didn't read it.
Q So you don't know what it says. Right?
A He's not in the regulatory department. My opinion was based primarily upon the regulatory process.
I did look for supporting evidence in terms of marketing of the product, the medical staff at Ethicon, Charlotte Owens and others in terms of their -- in terms of the support for the decision to go to market.
Q So let me ask you this: So if -- if the doctors and the people in medical affairs are telling the people in regulatory that this is a significant change, the Prolift is a significant change from any other prolapse surgery, and the people in regulatory decide to ignore that and not file a 510-K, that's okay?
MR. GAGE: Objection.
BY MR. MAZIE:
Q Is that what you're telling this jury?
MR. GAGE: Objection.
A Well, first of all, that's not the case. There was -- and I document deposition testimony

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referring to support and justification for the marketing.
So, I mean, your -- I don't know if it's a hypothetical you're presenting, but it's not factual.
Q I'm asking you to assume that the people in regulatory affairs ignored people in medical affairs and other consultants and ignored the fact that they were told that the Prolift procedure was a completely new procedure.
If that were the case, and based upon that they decided to ignore that advice and not file a 510-K, that would be okay with you.
MR. GAGE: Objection.
A What I -- what I see is that they did consider the medical opinion.
Q Let me ask you, what was the predicate device that Prolift -- I'm sorry. What is the predicate device that Ethicon compared the Prolift to in determining whether or not a 510-K was appropriate or necessary?
A Originally?
Q Yeah.
A Primarily the Gynemesh PS device that was previously marketed.
Q Well, only the Gynemesh -- Gynemesh PS.

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Correct? Initially.
A Well, there were other meshes on the market. There's other -- there's literature on other meshes, supportive evidence that was used as well. But the predicate was Gynemesh PS.
Q So fair to say that when it initially launched the product, Ethicon was comparing Prolift to Gynemesh PS. Correct?
A That was the predicate --
Q And --
A -- at the time.
Q And Ethicon came to the conclusion that there was no significant difference between the Prolift and Gynemesh PS.
A That's correct.
Q And because of that, it determined that a 510-K was not necessary.
A That's correct.
Q And if there was a significant difference in -- I'm sorry, between the Prolift as a procedure, as compared to the Gynemesh PS, that would have required a 510-K to be filed before the Prolift could be sold. Correct?
MR. GAGE: Objection.
A Can you repeat the question?

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Q Sure. If, in fact, there was a significant difference between the Prolift as a procedure, as compared to Gynemesh PS, that would have required Ethicon to have filed and obtained clearance through a 510-K before selling the Prolift. Correct?
MR. GAGE: Objection.
A Well, I think it would have been considered. Whether or not it would have resulted in a decision that it was significant enough, I mean, is another story.
In fact, I think that -- I mean, testimony shows, records show that -- that pelvic surgery using fashioned Gynemesh PS was -- was kind of the way people were doing things at the time, that urogynecologists were familiar with vaginal placement of the mesh, that they were using instruments to place the mesh.
So I -- you know, it's -- I mean, I guess you're -- if it's hypothetical, is a little bit of a stretch.
MR. MAZIE: Objection. Move to strike as nonresponsive.
BY MR. MAZIE:
Q I'm going to ask you again. I want you to assume that --

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MR. MAZIE: Strike that.
BY MR. MAZIE:
Q I want you to assume that the Prolift as a procedure, as compared to the Gynemesh PS, was a significant change. If that were the case, then Ethicon was required to submit a 510-K and obtain clearance from the FDA before selling the product. Correct?
MR. GAGE: Objection.
A I -- I think that stretches the limit of my expertise, and I would probably expect to get some input on that in order to fully gauge that.
Q I'll ask you one other way, and then we'll stop because we have a tape and we'll take a break. If the technique between the Prolift and the -- and Gynemesh was completely different, do you agree with me that a 510-K would have been required before Ethicon could legally sell the Prolift?
MR. GAGE: Objection.
A And repeat the question, please.
Q Sure.
A Yes.
Q If it was known to Ethicon that the Prolift procedure was completely different than that of Gynemesh PS, Ethicon would have been legally required

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to obtain 510-K clearance before legally selling the Prolift. Correct?
MR. GAGE: Objection.
A I don't think it's a -- it's a yes/no. I think they would have to assess that. Even if it was different, assess it, evaluate the significance of that difference, determine if it was significant according to the guidance, and then render a decision.
Q If it was completely different.
A I understand what you're saying.
Q Even if it was completely different procedure, you still think that they wouldn't need -- necessarily need a 510-K?
MR. GAGE: Objection.
A Well, what is completely different?
Q A revolutionary new procedure.
A What is revolutionary? It's in the eye of the beholder. Revolutionary procedure to one physician isn't a big deal to others, so ...
Q Let me ask you this: Have you reached a conclusion in this case as to whether the Prolift procedure represents a significant or substantial difference from that of the Gynemesh PS predicate?
MR. GAGE: Objection.
A Well, I didn't formulate an opinion

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specifically directed to that point. What I opined on was the process that Ethicon engaged in to render a decision that a submission was not necessary.
Q So just so we're clear and the jury is clear and the court is clear, you have not rendered in this case an opinion as to whether or not the Prolift procedure was -- I'm sorry, what was the term, significantly or substantially different? What's the legal --
A Well --
MR. GAGE: Objection.
BY MR. MAZIE:
Q What is the legal --
A Whether the new product was significantly different than the predicate.
Q Okay. You have not rendered -- just so the jury is clear and the court is clear, you have not rendered any opinion in this case as to whether or not the Prolift procedure is significantly different from that of the Gynemesh PS, the predicate device. Correct?
MR. GAGE: Objection.
A I'll refer to my opinions. I don't believe that was one of my opinions.
Q Okay.

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MR. MAZIE: We'll take a break, and you can let us know if you have that opinion.
THE WITNESS: Okay.
VIDEO SPECIALIST: The time now is 2:46. We are going off the record. This is the end of Disk Number 3.
(Short recess.)
VIDEO SPECIALIST: The time now is 3:06. We are back on the record. This is the beginning of Disk Number 4.
BY MR. MAZIE:
Q Okay. Mr. Ulatowski, before we broke I asked you a question, and I ask you it again. Are you rendering any opinion in this case as to whether or not the Prolift procedure represents a significant difference, as that term is defined in the regulations, from any -- the Gynemesh procedure or any other procedure?
MR. GAGE: Objection.
A I looked at my opinions during the break, and the most relevant opinion speaks to the process of -- that Ethicon followed regarding rendering the decision whether or not there was a significant change.
I didn't get into medical aspects of

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interpretation of medical-related issues.
Q Would it matter to you if the Prolift procedure represented a significant difference from the Gynemesh or any other procedure?
MR. GAGE: Objection.
A Significant difference how?
Q Completely new procedure. Completely different procedure that requires special skill or training by a physician before performing it.
MR. GAGE: Objection.
A Well, I -- I stayed away from any assessment of medical procedure because I thought it was extending the limits of my expertise.
Q Isn't that a critical determination as to whether or not the Prolift requires a 510-K clearance, as to whether or not the procedure is completely different from any other procedure?
MR. GAGE: Objection.
A Well, in my opinion I reflect upon what steps Ethicon took, how they filled out the flow charts, addressed the issues in the guidance, and rendered a decision.
They -- there was certainly information before the parties of the various things you've talked about, and the decision was what it was.

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Q The decision by Ethicon was that this was not a completely new procedure with -- which required a 510-K clearance before selling the product.
Correct?
MR. GAGE: Objection.
A The decision was that there was not a significant change between the predicate Gynemesh PS and the Prolift device.
Q And if there was a completely new procedure as part of the Prolift as compared to the Gynemesh, that would be a significant difference in accordance with the regulations, which would have required a 510-K clearance before Ethicon could sell the product.
Correct?
MR. GAGE: Objection.
A I didn't opine on that because that's something I would typically try to obtain some -- some clinical input on of my own choosing to -- to assist me in forming that opinion, if I -- if I wanted to form that opinion.
Q And if the clinical input -- if you went to the experts and they told you that the Prolift was a completely new procedure in which the surgeon would require special skill or training as compared to the Gynemesh PS predicate device, then that would lead you

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to the opinion that a 510-K would be necessary before Ethicon could sell the Prolift. Correct?
MR. GAGE: Objection.
A I -- I would stay away from that, as to limit my opinions in regard -- I would stay away from medical opinions.
I know that Gynemesh was -- Prolift was found equivalent to Gynemesh PS. Evidently there wasn't, according to FDA, a belief that things were all that different.
Q Do you know what the FDA actually looked at in making that determination?
A I've -- I've read the 510-K, the -- the amendments, all the information.
Q I want you to go back to Ulatowski 15, which is before you to your right. Your right there.
A Okay.
Q Which is the ten -- top ten learnings from the TVM. And I want you to look at the last bullet on the second page. It says, The TVM procedure was seen unanimously as a very innovative and novel way to do pelvic -- pelvic -- POP, which stands for pelvic organ prolapse surgery.
Do you see that?
A I see the sentence.

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Q If the Prolift was a very innovative and novel way to do the prolapse surgery as compared to the Gynemesh predicate, that would be a significant difference which would require a 510-K clearance before Prolift could be sold. Correct?
MR. GAGE: Objection.
A I just didn't formulate an opinion. I think I need various input in order to render an opinion on that.
Q All right. Let me give you some more input. I'm going to show you -- did we mark this? We marked this. Okay. I want you to look at -- this is deposition, portions of the deposition of Dr. Axel Arnaud. And I'm going to ask you to look on Page 75, Line 2.
A This one you gave me before?
Q Yes.
A Okay.
Q It's Page 76, Line 4. I'm going to read this to you. I'm going to ask you to read along.
A When was this deposition, by the way?
Q You can look on the front. This was taken on November 15th, two weeks ago.
A Oh, okay. That's why I didn't review it. Yeah. Okay.

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And what page is that?
Q Seventy-five.
A Okay.
Q Line 2.
A It came after my report.
Q Well, you were supplementing your report. Correct? After your initial report. Right?
A And I probably will do again, perhaps.
Q Well, that -- that remains to be seen as to whether you can do that under the court rules.
But you've -- you've given us updated materials as of two days ago. Right?
MR. GAGE: Objection.
A I don't know what counsel has provided you.
Q Well, I gave you that. We marked that earlier in the deposition.
A Oh, the supplement? Okay.
Q Right?
A If that's what you're talking about.
Q As you reviewed stuff you provided us an updated Exhibit B. Correct?
A Yes.
Q Okay.
A Right.
Q And this certainly was something that, it

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was taken two weeks ago, you certainly could have commented on this if you wanted to, correct, Dr. Arnaud's deposition?
A Well, if I had it and there was sufficient time, perhaps.
Q Now, Page 75, Line 2. Are you there?
A Yes.
Q This is Dr. Arnaud, who is one of the innovators of the Prolift procedure. Correct?
MR. GAGE: Objection.
A If you -- I mean, I'm assuming so, based on your statement, but -- you know.
Q "QUESTION: So if somebody were to suggest to you that the Prolift was not significantly different in any way from Gynemesh, you would strongly disagree with that?
"ANSWER: Well, it depends what you mean by Prolift, because Prolift is both procedure and product. So --
"QUESTION: I'll answer your question, make it clearer. If somebody were to say the Prolift, the entire system, including the procedure, the mesh and the instruments as it was sold, as compared to Gynemesh as it was sold, if someone were to say that Prolift did not have any significant differences from

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Gynemesh, you would disagree with that statement?
"ANSWER: Well, there are aspects that are similar. The material's the same. So the tolerance is likely to be the same. Now, the size is completely different. The aim of the Prolift was to create a barrier to all the potential defects in the pelvic floor, a whole barrier. So that was not all the case with the Gynemesh. So in some way the mesh is the same. But the technique is completely different."
Do you see that?
MR. GAGE: Objection.
A I see -- I see what it says.
Q And do you see that Dr. Arnaud, one of the -- the top minds at Ethicon with regard to the development of the Prolift, testified under oath that the Prolift procedure is completely different from Gynemesh. Do you see that?
MR. GAGE: Objection.
A I see it.
Q Do you have any reason to disagree with Dr. Arnaud that the Prolift procedure is completely different?
MR. GAGE: Objection.
A I'm not a physician. I've -- I don't know on what basis I would disagree with a clinical

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statement.
Q Do you know if special skill or training is required in order for a physician to safely and effectively perform the Prolift procedure?
A Well, I know what the labeling states. And it speaks of training, there's a training program. Of course those people using it are board-certified urogynecologists with years of training. So in that sense, there's skill and training.
Q This is my question: Do you know -- well, first of all, you understand that the labeling says the training is available. Right?
MR. GAGE: Objection.
BY MR. MAZIE:
Q That's what it says.
A In what -- in which particular IFU?
Q In any of the IFUs that talk about training. They say training is available and recommended. Corrected?
MR. GAGE: Objection.
A I understand it's in at least one. I recall the statement, yes.
Q Okay. If it was necessary, if Ethicon knew --
MR. MAZIE: Strike that.

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BY MR. MAZIE:
Q If Ethicon knew that training of the surgeon was necessary in order for the surgeon to safely and effectively perform the Prolift procedure, that would be a significant difference that would require 510-K clearance. Correct?
MR. GAGE: Objection.
A The reason I pause is, is I've been confronted with the same sort of question in other 510-Ks. And sometimes the answer is yes, sometimes the answer is no. It -- it's based on medical input, clinical input I receive on assessing that training, assessing the fundamental skills of the surgeons.
So I can't say with certainty exactly that to be the case.
Q I want you to assume that the people in medical affairs as well as the medical consultants told Ethicon that in order for the Prolift procedure to be safely and effectively performed, the surgeon has to have training, special training, in the Prolift. I want you to assume that.
If that were the case, and then Ethicon was told that by its medical consultants, that would have required them to submit a 510-K for clearance before selling the Prolift. Correct?

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MR. GAGE: Objection.
A I -- I need some medical input on that. May be the case, may not be the case. I can't -- I can't concede.
Q Let me give you the medical -- fine. I'll give you the medical input.
MR. MAZIE: Mark this.
(Ulatowski Exhibit 17 marked for identification, to be attached to the transcript.)
(Discussion off the record.)
BY MR. MAZIE:
Q This is the deposition of Dr. Lucente. Okay? You understand Dr. Lucente to be one of the top consultants of Ethicon prior to the launch through the -- through the time that Ethicon stopped selling the Prolift. Correct?
MR. GAGE: Objection.
A Well, I know he's been involved with Ethicon. I don't know his status as far as top whatever. He's certainly a consulting person.
Q Do you understand that Dr. Lucente was involved in the American TVM study?
A I believe so, but I'd have to see my records in regard to that. But I'll take what you're saying on its face.

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Q And do you know that representatives of Ethicon described Dr. Lucente as one of their top medical consultants concerning the Prolift?
MR. GAGE: Objection.
A I -- I don't recall that testimony, but I hear you.
Q All right. I'm going to ask you to turn to -- by the way, did you ever see this deposition before?
A Lucente, yes. I -- yeah, I remember Lucente. But let me just refer to my list just to make sure.
Q It's not on your list, Doctor. I mean -- I'm calling you doctor. It's not on your list, Mr. Ulatowski.
A I guess it's the records that I reviewed. I don't have my list in this document here.
Q Why don't you take a look at your updated Exhibit B, because it's not on there. I want to make sure that you haven't seen it.
A Yeah. Well, there's certainly testimony -- reference to him and testimony and whatnot. That's probably what I'm recalling.
No, I haven't reviewed the deposition. But, you know, it's as I said.

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(Discussion off the record.)
BY MR. MAZIE:
Q So you never saw the deposition of Dr. Vincent Lucente. Correct?
A Evidently not.
Q Okay. I want to ask you to turn to Page 252 of the deposition. And I'll read to you from 252, Lines 4 to 12.
A Okay.
Q "QUESTION: Just so I'm clear, you would discuss with Ethicon prior to the launch of the Prolift in February of 2005 that surgeons as a whole, unless they were world-renowned top surgeons with special expertise, putting them aside, surgeons as a whole would have to have special training in order to safely perform the Prolift procedure. Correct?
"ANSWER: Yes."
Do you see that?
A Yes, I see that.
MR. GAGE: Objection.
BY MR. MAZIE:
Q Okay. So Dr. Lucente, one of Prolift's medical consultants, told Ethicon that surgeons would have to have special expertise to safely perform the Prolift procedure prior to the launch of the Prolift.

Correct?
MR. GAGE: Objection.
A Well, it's -- it's what you stated.
Q That's what Dr. Lucente testified to under oath.
A That's what was stated in the deposition.
Q Correct?
A Whatever the exact words. I closed up the page.
Q If Ethicon agreed with that fact, do you agree with me that a 510-K would be necessary before Ethicon could legally sell Prolift? Correct?
MR. GAGE: Objection.
A Well, first of all, take me back to that page.
Q 252, Lines 4 to 12.
A Okay.
I would probably get some medical input. But training, the need for training and whatnot, is -- is almost an element of every device.
Q Let me ask you this: If the -- if the Prolift procedure was so novel that Ethicon itself, prior to launch, was of the opinion that in order for a physician to safely and effectively perform the Prolift procedure, that they had to have special

training, you agree that a 510-K would have been required before Ethicon could sell the Prolift.
Correct?
MR. GAGE: Objection.
A I think, again, based on opinion conversation with medical input, it -- the answer may be no.
Q What if Ethicon came to that conclusion itself? Forget you and your forensics, which you haven't done here. I'm asking you, if Ethicon came to the conclusion that in order for a physician to safely and effectively perform the Prolift procedure, you have to have special skill and training, if that's the scenario, then they had to have a 510-K in order to sell the Prolift. Correct?
MR. GAGE: Objection.
BY MR. MAZIE:
Q If you assume that.
MR. GAGE: Objection.
A I -- I don't agree with that. It would -- I mean, it wasn't something I rendered an opinion on. I would probably need some medical input on that.
Q Let me give you more medical input. Turn to Page 254 of Dr. Lucente's deposition.
A 254?

Q 254. Let's read Lines 12 to 19.
"QUESTION: Doctor, you agree that you had conversations with the leadership at Ethicon prior to February of 2005 wherein the leadership of Ethicon and you agreed that surgeons had to have special training in the Prolift procedure in order to safely and effectively perform the procedure?
"ANSWER: Yes."
Did I read that correctly?
MR. GAGE: Objection.
A I believe so.
Q So we know that according to Dr. Lucente's sworn testimony, the leadership at Ethicon was of the opinion before the launch of the Prolift that in order for surgeons to safely and effectively perform the procedure, that they had to have special training.
Correct?
MR. GAGE: Objection.
A That was the statement.
Q And if that's the case, and we accept Dr. Lucente's testimony as true, that would require a 510-K clearance by the FDA before Ethicon could sell the Prolift. Correct?
MR. GAGE: Objection.
A Ethicon considered all this input. They

rendered a decision 510-K was not necessary.
Q Well, I understand. But we've already gone over that they can intentionally ignore or they can make mistakes.
I'm asking you, if they were -- if they were of the opinion, the leadership at Ethicon were of the opinion that here we have this new device known as the Prolift, and you need special skill and training in order to safely and effectively perform the procedure, if that's what they -- their conclusion was, then they had to have a 510-K in order to say -- to sell the product. Right?
MR. GAGE: Objection.
A They knew this information. They rendered a decision with their eyes wide open as far as submission, as far as what I can tell from the records.
Q So they knew and they made a decision that there was no 510-K necessary, they knew at Ethicon that you needed special skill and training to safely and effectively perform the procedure. Correct?
MR. GAGE: Objection.
A Well, that they -- you needed? The labeling says you -- it isn't imperative. It says, I think, training is available. You, yourself, pointed

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that out to me.
Q Right. And the labeling contradicts the sworn testimony of Dr. Lucente, does it not?
MR. GAGE: Objection.
A Well, training -- the labeling is what it is. I don't know if it contradicts it. Because training is available to whom, under what conditions, based on what expertise. You know, board-certified urogynecologist, do they get the same training as one who is not board -- you know, I -- I need -- I would probably explore that with medical personnel.
I understand what these people are saying as -- as -- as medical staff, but I didn't -- I didn't digest this and formulate an opinion on it in my report.
Q Well, again, Dr. Lucente said -- testified under oath that Ethicon agreed that surgeons had, used the word "had," to have special training, regardless of who you were, to safely and effectively perform the Prolift procedure. That contradicts the labeling, does it not?
MR. GAGE: Objection.
A Well, this is an input from an individual who is in the process. Ultimately the -- as the process unfolds, decisions are made, inputs

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considered. Process ensues, 510-K or no 510-K.
Q Well, I'm not talking about an individual; I'm not talking about Dr. Lucente's opinion. I'm telling you that according to Dr. Lucente under oath, it's the leadership of Ethicon that was of the opinion that surgeons had to have special training in the Prolift procedure in order to safely and effectively perform the procedure. Right?
MR. GAGE: Objection.
A That's his impressions and opinions and recollections, I suppose.
Q And if he's correct that the leadership of Ethicon agreed and was of the opinion that surgeons had to have special training in the Prolift procedure in order to safely and effectively perform the procedure, then a 510-K would have been required, if Ethicon was of that opinion. Correct?
MR. GAGE: Objection.
A No, the process was considered and decision made. I -- I've -- in my experience have seen special training and whatnot for lots of products come along where there's been no 510-K.
Q Does that mean it's the right decision?
A Very much so.
Q So in this instance, even if there's a

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substantial -- I'm sorry. If the Prolift procedure is significantly different from Gynemesh, even if -- even if that's the case, it's okay not to get a 510-K as long as Ethicon comes to the conclusion they don't need it. Is that what you're telling this jury?
MR. GAGE: Objection.
A What -- what I'm telling the jury is, I would need to assess this based upon medical opinion to determine, based upon my own evaluation, the import of it.
I think you're showing me deposition testimony. These aren't things that I take lightly. I would evaluate these things over days at FDA, with back and forth with the people making the opinions. These -- sometimes these things have to be challenged, they're considered.
I'm -- I'm not going to be contesting what medical officers are saying. I'm not a urogynecologist. But, you know, on the flip side, I'm not going to be making a -- a final medical opinion about novelty or uniqueness or special training.
My opinions were, I saw the process, I saw the basis for the process, I saw the decision made.
Q I understand that your testimony is that the process they performed at Ethicon was appropriate.

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Is that correct?
A Yes.
Q Okay. My question is, are you rendering an opinion as to whether the decision that was made by Ethicon, taking into consideration all variables, including medical consultants, whether that was a proper decision not to submit a 510-K?
MR. GAGE: Objection.
A Well, let me turn to my opinion, and I'll tell you exactly what I said.
Q Well, do you really need to read your own opinion to tell you that?
MR. GAGE: Objection.
A Well, I don't know about you, but I can't memorize 74 pages. And I want to be as accurate as possible as well.
Q You want to be as accurate as possible in your -- in your answers. Correct?
A Yes.
Q And that would mean taking into consideration all evidence that you become aware of. Correct?
A As much as I can consider it within the limits of my expertise.
Q Okay. Let me know what your opinion is.

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A My opinion was Ethicon legally marketed Prolift from March '05 to August '07.
Q Okay. Now can you answer my question? My question was, we know that you've given an opinion --
A Yes.
Q I'm sorry. Are you done?
A Can I go further?
Q Sure.
A Thank you.
As evidenced by the following. The manufacturer makes the decision. If the manufacturer determines that change is not significant, 510-K is not required. I concurred with FDA's opinion regarding the process of -- that Ethicon used.
Ethicon documented the rationale. Ethicon was not required to contact FDA to obtain their opinion.
So I was -- I was speaking to process, documentation. I didn't say, Well, medically, putting trocars in here or doing this or that is different than doing this or that otherwise in the vagina or outside the vagina. That's not my expertise area.
Q Let me ask you this: I understand that you rendered an opinion that the process followed by Ethicon was -- was proper. Right?

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That's one of your opinions?
A Yes.
Q Okay. My question is, are you rendering an opinion in this case as to whether or not the decision, the ultimate decision made by Ethicon not to submit a 510-K, was appropriate?
A I didn't render an opinion there.
Q Okay.
A Except, you know, in terms of process, just that.
Q Again, I want to have clean answers from both of our perspectives.
I know you rendered an opinion that the process that was followed by Ethicon was appropriate.
Correct?
A Yes.
Q Okay. You have not rendered an opinion in this case as to whether or not the decision, ultimate decision as to whether or not to submit a 510-K by Ethicon, was proper or not. Correct?
A I didn't technically and medically scientifically dissect the underlying elements of that decision process.
Q And you didn't reach a conclusion as to whether they made a proper decision or not.

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A I -- I don't --
MR. GAGE: Objection.
A Well, let me read again my -- just to be exactly sure and accurate.
That's not an element to my first opinion, the decision of -- yeah.
Q Okay. Or any opinion. You say your first opinion. It's not an element of your opinion. You're not rendering such an opinion in this case. Correct?
A I don't believe so.
Q Okay. All right.
(Discussion off the record.)
BY MR. MAZIE:
Q Do you know if Catherine Beath, the head of regulatory, knew whether or not special training was necessary to safely and effectively perform the Prolift procedure?
MR. GAGE: Objection.
A I'd have to review my report to -- to look at --
Q All right. Why don't you take a look at your report.
A -- testimony that might be relevant.
(Ulatowski Exhibit 18 marked for identification, to be attached to the transcript.)

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A Well, the only -- well, one quote I have on Page 52 is, Ethicon followed the guidelines, circled the right areas, and came up with the decision and conclusion that no 510-K was required.
That's one quote I have.
I don't see, I mean, with a quick look, any other quotes directly to Catherine.
Q Why don't you take a look at Ulatowski, what number is that, 16?
A Eighteen.
Q Eighteen.
Have you seen this testimony before by Ms. Beath?
A Let me see. March 26? Yeah, I believe so. I believe I received all her deposition testimony.
Q Okay. Let's look at Page 501. I'm going to read it to you. Lines 2 to 20 --
MR. GAGE: Do you have another copy?
BY MR. MAZIE:
Q -- of Catherine Beath's sworn testimony.
MR. GAGE: Would you give me those pages and line again?
MR. MAZIE: 501.
BY MR. MAZIE:
Q "QUESTION: The form for Gynemesh says

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special training is not needed for safe and effective use of the device. Correct?
"ANSWER: That's what it says.
"QUESTION: Okay. And you would expect that to be accurate. Right?
"ANSWER: This one looks like a complete file. I think there might be even -- there might even be a signature. It's the second one. I don't know what it is or where it came from.
"QUESTION: Okay. So for Gynemesh, you know that Question 7 is answered appropriately, that special training isn't needed for safe and effective use of the device. Correct?
"ANSWER: Yeah. I know from the risk assessment that they did with the medical and quality engineers that the -- that's the conclusion they came to."
Do you see that?
A Yes.
Q Do you have any reason to disagree with the sworn testimony of Catherine Beath, the regulatory head at Ethicon, that special training was not required of Gynemesh?
MR. GAGE: Objection.
A Yeah, I was just puzzled by, you know, this

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reference to Question 7 and whatnot, trying to understand the context, where she's coming from. I mean, she's saying in the last past, I know from the risk assessment that certain people came to that conclusion. Quality -- medical and quality engineers.
And so your question was, again?
Q My question is, regulatory -- regulatory at Ethicon came to the conclusion that special training was not necessary to safely and effectively utilize Gynemesh PS. Correct?
MR. GAGE: Objection.
A I guess in this one instance with this one file. I guess I'm having trouble taking this out of context to understand what she's saying here.
Q Well, do you know whether or not you need special skill or training to safely use Gynemesh outside of the Prolift procedure?
MR. GAGE: Objection.
A Well, I know that there was -- there was training provided for people.
Q For Gynemesh or for --
A No.
Q -- Prolift?
A For Prolift.
Q I'm asking you about Gynemesh. Aside --

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putting Prolift aside, do you have any reason to dispute the sworn testimony of Catherine Beath that if you're using Gynemesh outside of the Prolift procedure, you don't need special skill or training?
MR. GAGE: Objection.
A Reflecting on what she's saying here, if I'm understanding her correctly, she's responding in the affirmative that it's not in the labeling for Gynemesh.
Q Do you have any reason to dispute that you don't need special skill or training to utilize Gynemesh outside of the Prolift procedure?
A I mean, based on this, that seems to be the case.
Q Okay. And if you don't need special skill or training to use Gynemesh but you need special skill --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q If you don't need special skill or training to use Gynemesh but you need special skill or training to safely and effectively perform the Prolift procedure, that would be a significant difference between the two products. Correct?
MR. GAGE: Objection.

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A That would be a difference. It would be assessed in the 510-K decision tree process, and the decision made whether to submit or not submit.
Q And if it's a significant difference, that would lead to the conclusion, by using the decision tree, that a 510-K is necessary before the Prolift can be sold. Correct?
MR. GAGE: Objection.
A Just talking a process. If the -- there's a decision by regulatory that a change is significant, according to the regulations, as further discovered, assessed by the guidance, so if it's significant per the regulations, then an application is required.
Q And if an application is not made, it's illegal to sell the Prolift.
MR. GAGE: Objection.
A Well, first of all, regulatory made the decision. And based on the information it had, it followed -- it brought to bear a decision made not to submit.
And, again, at the back end, you know, again talking to process. Nothing is automatically identified as misbranded or adulterated. That's subject to FDA assessment.
Q Can I ask you, the instruments themselves,

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they're all part of the procedure. Correct?
MR. GAGE: Objection.
A Well, the instruments are part of the kit which are used in the procedure.
Q And they're specially designed for the procedure. Correct?
A They were included in the kit to be used in the procedure. Specially designed? I don't know. I'd need an engineering assessment of that.
Q Did Dr. Arnaud help you with that?
A No, an engineering assessment.
Q You need an engineering assessment as opposed to one of the -- the people who were the creators of the Prolift procedure?
MR. GAGE: Objection.
A Well, you used the term "specially designed." I mean, when products are created, they're in the broadest sense specially designed to meet a -- to meet the design requirements.
So were they so different from other devices? Evidently Ethicon thought they were -- they were -- there were similarities.
So were they specially designed? You know, it's -- it's how you want to characterize it.
Q Where did Ethicon think -- where did --

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where do you get that from, that Ethicon thought that the procedure between Prolift and Gynemesh or any other procedure were similar? Where is that from?
MR. GAGE: Objection.
A You know, what I was reflecting upon was -- were the Project D'Art strategy documents where the instruments were discussed and characterized. So that's what I'm referring to.
Q When you're evaluating whether or not to submit a 510-K for the Prolift, you look at the entire procedure as a whole?
A Say that again, please.
Q Do you look at the entire procedure as a whole when you're evaluating whether or not to perform -- to submit a 510-K for the Prolift?
A Now you're putting me in the shoes of Ethicon, basically?
Q Yes.
A Well, I didn't render an opinion on exactly what they considered; I opined on the process they used to render an opinion.
Q Okay. So you have no opinion on -- as to what Ethicon did or did not consider in arriving at its decision not to submit a 510-K.
A I looked at the flow charts that they

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filled out, the decisions made according to the guidance, and conclusions they made based upon that assessment.
Q I understand that. My question is -- let me go back.
(Discussion off the record.)
BY MR. MAZIE:
Q Is it fair to say you did not render an opinion on what Ethicon did and did not consider in performing its 510-K evaluation?
MR. GAGE: Objection.
A Well, you can't divorce -- if one fills out the flow chart, you see what they were thinking in regard to the assessment of -- of differences of the predicate to the new device, the Prolift device. Technological characteristics, labeling. So they were considering technological characteristics.
(Discussion off the record.)
BY MR. MAZIE:
Q When you were performing your expert work, did you look at the entire procedure as a whole that was performed by Ethicon in determining whether or not a 510-K should be submitted --
MR. GAGE: Objection.
BY MR. MAZIE:

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Q -- or is required to be submitted?
A I think I've stated, you know, how I formed my opinion and what my opinion is based upon.
I certainly looked at labeling, the procedure, all that information. But as far as assessing the procedure, I'm not a urogynecologist; I'm not going to render a medical opinion on this procedure versus that procedure or changes in procedure.
I saw deposition testimony. I've seen the testimony today. I saw testimony from the medical staff saying, you know, we've been in the pelvic space, we've been using instruments, we've been cutting Gynemesh all kinds of shapes, sticking it into the vagina. FDA took a look at this eventually. There's no new issue here, they said.
So, you know, it is what it is. I guess from -- from that point of view.
Q And you're not rendering any opinion as to whether or not it is a new issue in the Prolift procedure. Correct? You're only --
MR. GAGE: Objection.
A I know that FDA did not consider there to be new issues.
Q I'm not asking about the FDA. We'll ask

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about the FDA either later or tomorrow.
You're not rendering any opinions here as to whether anything was new vis-à-vis the comparison between the Prolift and Gynemesh. Correct?
A Well, within the context of their decision process. Again, looking at what they did, how they filled out that chart, what did -- that chart tells you what they were thinking of, what they considered.
Now, behind that is all of that documentation, all that testimony, all that engineering and science. Which is summarized in those flow charts, basically.
I didn't go back to all that stuff to assess that. I looked at the chart.
MR. MAZIE: Let me mark that.
(Ulatowski Exhibit 19 marked for identification, to be attached to the transcript.)
BY MR. MAZIE:
Q Do you know what this is?
A It is a Project D'Art document.
Q Is this one of the documents that you reviewed and relied upon in coming to your opinions in this case?
A Let me examine my report.
Q Sure.

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A This is what date? February 28 of '05.
I don't see it in one section. Let me turn to my reliance list, see if it's on there. This looks familiar, but -- but let me turn to that.
You know, I don't -- hang on a second.
Yes, I did see this.
Q Yes. This is the final DDSA. Correct?
A Yes. Uh-huh.
Q And it's dated February 28, 2005. Correct? Look at the second page.
A Yes.
Q And you reviewed and relied upon this document in arriving at your opinions. Correct?
A I -- I think I reviewed it and commented on it. As far as referring to it in my opinions, I did -- well, is it -- it's in my report. I formulated my opinions based upon -- partially by evaluation of this.
Q And one of the things that you did is rely on this document, because this is an important regulatory pathway document. Correct?
A DDSAs --
MR. GAGE: Objection.
A -- are important.
Q And critical?

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MR. GAGE: Objection.
BY MR. MAZIE:
Q To the process, the regulatory process. Correct?
A Well, lots of things are -- are -- I call it important. Whether it's a critical document, there's lots of -- I wouldn't want to raise it to that level.
Q If the regulatory process that you opined on at Ethicon, if they came to the conclusion that there were no predicate devices to the Prolift, that in and of itself would require them, under the decision trees, to submit a 510-K before selling Prolift. Correct?
MR. GAGE: Objection.
A If the regulatory group under Catherine Beath decided it could not identify a predicate, that would be a problem.
Q And it would be such a problem that that would have required them to have submitted a 510-K before selling the Prolift. Correct?
A You'd have to have a predicate in order to attach the new product to.
Q And if you didn't have a predicate product, then you couldn't legally sell and market the Prolift

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to doctors for implantation in women. Correct?
MR. GAGE: Objection.
A Well, it's all theoretical, because Gynemesh PS was the predicate.
Q I'm asking you if the determination through the process at Ethicon was that there was no predicate device for Prolift, if that were the case -- I want you to assume that -- and Ethicon nevertheless did not submit a 510-K and went ahead and sold the Prolift to physicians for implantation in women, that would be an illegal marketing of the Prolift. Correct?
MR. GAGE: Objection.
A If Gynemesh PS didn't exist and there was no other reasonable predicate that regulatory group could identify and did not identify, that would be a problem.
Q That would be an illegal marketing of the Prolift. Correct?
MR. GAGE: Objection.
A Well, FDA would assess that and render a charge, if necessary.
Q Let me ask you this: If Gynemesh existed but hypothetically Ethicon came to the conclusion that Prolift -- I'm sorry, if gyn -- let's assume Gynemesh exists. Okay?

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A It does.
Q Right. So I want you to -- this is the question.
A Okay.
Q If -- I want you to assume hypothetically that Ethicon came to the conclusion that there was no predicate device to Prolift, that Gynemesh was not a predicate device. Okay? Under that scenario, they could not legally market and sell the Prolift without getting clearance from the FDA. Correct?
MR. GAGE: Objection.
A Ultimately that responsibility was Catherine Beath's group. Did they make that determination, Catherine Beath's group? No, they didn't.
Q I'm --
A So, I mean, you're saying if Ethicon made -- well, some engineer somewhere in the organization says there's no predicate. Well, that's nice to say that, but ultimately the regulatory group makes that determination, upon assessment of their products and everyone else product -- else's products on the marketplace.
I've -- again, I've had customers come to me and say, Well, we have no predicate. Well, I'm --

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you'll be delighted to hear there's lots of predicates out there --
Q Okay.
A -- so ...
Q Well, let me ask you this: If in the DDSA the regulatory group came to the conclusion that there was no predicate device, do you agree with me that Ethicon could not legally market and sell the Prolift for implantation into women without first obtaining FDA clearance? Correct?
MR. GAGE: Objection.
A Well, it's not where you start; it's where you end up. What was the -- what was the -- prior to marketing, what was the final decision? And documented decision? When FDA comes in and looks at the documentation of the decision, what was the decision, how was it documented, was it valid documentation.
Q Is this --
A Documentation is, there's Gynemesh PS out there.
Q Is this the final DDSA? Doesn't it say that?
A Well --
MR. GAGE: Objection.

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A This is a document.
Q Does it say it's the final DDSA? Look on the first page. First page.
No. First page. Look on the side. It says 05 Final DDSA.
A Yes.
Q Do you see that?
A Uh-huh.
Q And then the -- correct?
A That's what it says.
Q And on the second page, it's dated February 28, 2005. Correct?
A Yes.
Q This is the DDSA within a week of the launch of the Prolift. This is the final one.
Correct?
MR. GAGE: Objection.
A It may well be. By those dates I would think it would be.
Q Okay. And if in this DDSA it says that there are no predicate devices, because this is a regulatory document from Catherine Beath's own division, if this says there's no predicate device, then Ethicon should not have sold the Prolift without first obtaining FDA clearance. Correct?

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MR. GAGE: Objection.
A Well, who's -- who's Jeffrey Everett, first of all?
Q Do you know who Scott Ciarrocca is?
A I don't recall his title. I mean, I told you people I knew.
Q Let's do this.
A O'Bryan, Beath.
Q Fine. Let's go to page -- let's go to the third page of this document. Okay?
A Okay.
Q The people involved here -- first of all, the Prolift project leader, Scott Ciarrocca, right, he's listed on this document. Right?
A Yes.
Q Okay. You have the manufacturing technical services engineer, Sunny Rha. She's on here.
Correct?
A Yes. Uh-huh.
Q Okay. You've got the development engineer and scientist of Prolift, Rod Simpson.
He's listed on here. Correct?
A Uh-huh.
Q Correct?
A Yes.

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Q You've got the quality assurance engineer, Jeffrey Everett, from Prolift, listed on here. Correct?
A Uh-huh.
Q You've got to answer verbally, sir.
A Yes. Sorry.
Q You've got Sean O'Bryan of regulatory affairs on this document. Correct?
A His name is here, yes.
Q Okay. This is the final DDSA which has been signed off on a week before the launch of the Prolift. Correct?
MR. GAGE: Objection.
A Hang on a second. The reason I paused is, I see an analysis team and the associate name. I don't see any sign-offs, though.
Q Do you see the memo?
A I mean, you can direct me further.
Q The second page. The summary memo that's sent by Jeffrey Everett. This is the final product DDSA. It's the first sentence. You haven't seen this before?
A No, I've seen it before.
MR. GAGE: Objection.

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A Okay. Electronically approved.
Q Right? So let's go back.
A Okay.
Q This is the final DDSA from Catherine Beath's group. Correct?
MR. GAGE: Objection.
BY MR. MAZIE:
Q At Ethicon for the Prolift. Yes?
MR. GAGE: Objection.
A I assume that to be the case, just based upon the date and when marketing began.
Q Okay. And if this document, which was signed off on a week prior to the Prolift launch, said there is no predicate device to Prolift, then it would be illegal for Ethicon to sell the Prolift without FDA clearance. Correct?
MR. GAGE: Objection.
A Well, it's -- it's clearly in contradiction to other documentation by the regulatory group.
Q I'm asking you a question. If Catherine Beath's group came to the conclusion that there is no predicate device to Prolift, they could not legally market and sell Prolift for implantation into women's bodies without FDA clearance. Correct?
MR. GAGE: Objection.

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A They did make the determination there was a predicate, notwithstanding this document.
Q Did you hear what I said, though? I want you to assume that Catherine Beath's group came to the conclusion that there is no predicate device to the Prolift. I want you to assume that. If that were the case, it would be illegal for Ethicon to market the Prolift before obtaining FDA clearance. Correct?
MR. GAGE: Objection.
A Catherine Beath's group determined there was a predicate.
Q I want you to assume -- you're refusing to answer my question?
A I see this document.
MR. GAGE: Objection.
A I see this other document.
Q I want --
A Your assumption is --
Q I want you to assume -- I'm asking you to assume a hypothetical. That's what I'm asking you to assume. Okay?
A It's --
Q It's a hypothetical.
A It's kind of incomplete to me, I suppose.

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Q I'm asking you to assume a fact. I want you to assume that Catherine Beath's regulatory group at Ethicon came to the conclusion that there was no predicate device to Prolift. If that were the case, Ethicon would be illegally marketing the Prolift if it did not first obtain FDA 510-K clearance. Correct?
MR. GAGE: Objection.
A Well, I think underlying your -- your hypothetical is that there's some document that says one thing, and you're going to hang your hat on it. I'm hanging my hat on the regulatory documentation that they had under Project D'Art that there was a predicate, they followed the flow chart, and they made the decision not to file.
Q I'm going to get the judge on the phone. Are you refusing to answer this question?
A I'm not. I'm just --
MR. GAGE: Objection.
A You're arguing with me. I've asked you the same question five times. All I want you to do is make an assumption. I understand you disagree with that assumption. That's clear in the record. You're refusing to answer a question. I'm asking you to assume that Catherine Beath and her regulatory group at Ethicon came to the conclusion

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that there was no predicate device to Prolift.
If you make that assumption, it would have been illegal for Ethicon to market and sell the Prolift device without first obtaining 510-K clearance from the FDA. Isn't that correct?
MR. GAGE: Objection.
A Well, on the front end, the regulatory group would have to document in their history file, without contradiction, uniformly, consistently, as a final document to support marketing, from regulatory group, under the process that I opine on, first identifying the predicate, first -- then going through the process. If they can't get past the predicate, there's a problem.
So, I mean, that's my answer. The -- the fact of the matter is, there was a predicate.
MR. MAZIE: Objection. Move to strike.
BY MR. MAZIE:
Q I'll do it again.
I want you to assume after performing their entire process, regulatory process, that Catherine Beath's group came to the conclusion that there was no predicate product for the Prolift. Can you make that assumption for me, even though you disagree with it?
MR. GAGE: Objection.

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A The reason I -- I -- I'm struggling with that is because you have one document here that -- that says one thing. Show me the documents from Project D'Art and the decision tree where they concluded there was a predicate.
Q We'll get there. I'm asking you to assume after performing all their analysis --
A So if you erase all that other documentation.
Q I'm asking --
A That goes away?
Q I'm asking you, after performing the decision tree, after doing the DDSA, after doing the FMEA, everything, their conclusion at the time of launch is that there is no predicate product. I want you to assume that. Okay?
With that assumption, do you agree with me that if that was the case, that they assumed that there was no -- they came to the conclusion that there was no predicate product for the Prolift, that it would have been -- would have been illegal for Ethicon to sell the Prolift without first obtaining FDA clearance?
MR. GAGE: Objection.
A That's kind of the -- an aspect of my first

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opinion. My opinion being, they went through the process, made the right -- had the right documentation, had the predicate.
The flip side is if you can't do that, then there's a problem. So I'm answering your question by saying, well, yeah, if you can't document it, if you can't do what I just said, you've got a problem.
Q Let's turn to Page 3550 of the DDSA, final DDSA.
Are you there?
A Yes.
Q This is the use-related hazard worksheet.
Do you see that?
A Yes.
Q It says, "Have safety or efficacy issues occurred in the use of predicate or other similar devices."
Do you see that?
A Yes.
Q And it says to the right, "No known predicate/similar devices."
Do you see that?
A Yes.
Q That was a conclusion of the DDSA and the regulatory group at Ethicon. Correct?

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MR. GAGE: Objection.
BY MR. MAZIE:
Q The week before launch. Right?
MR. GAGE: Objection.
A I see that. I guess I'm -- you know, I've seen this before. I -- I don't understand the context of this. I don't understand how they came to this, because Gynemesh PS was out there.
Q They came to the conclusion --
A Somebody came to --
Q -- that Gynemesh PS -- no. This is signed off by the entire regulatory group, is it not? This is a DDSA.
MR. GAGE: Objection.
A Do people make mistakes?
Q Well, the question is, what's the mistake. Right?
A That there was a predicate.
MR. GAGE: Objection.
BY MR. MAZIE:
Q Or maybe there wasn't a predicate, and that's the mistake. Right?
A Well, I think FDA agreed there was a predicate, Gynemesh PS.
Q Well, we'll get to that.

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But the question here is, we don't know who -- what mistake was made and by whom at Ethicon, do we?

MR. GAGE: Objection.

BY MR. MAZIE:

Q Because this says there was no predicate. Right?

MR. GAGE: Objection.

A It says what it says.

Q Let's go now to Page 3565.

Third column under Comments. It says, "Currently there is no equivalent product indicated for this procedure."

Do you see that?

A Let me just read -- I see that. But let me just see the context here.

I see that.

Q And they're referencing Gynemesh and Prolift. Correct? Right next to it?

A They have Gynemesh there listed.

Q And Prolift. Correct?

A And Prolift, yes.

Q And they came to --

A And the other studies.

Q And they came to this conclusion days

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before the launch of the Prolift, that currently there is no equivalent product indicated for the Prolift procedure. Correct?

MR. GAGE: Objection.

A Well, I see what's stated.

Q And you have no explanation as to why in the DDSA Catherine Beath's regulatory group came to the conclusion that there is no predicate device for the Prolift procedure. Correct?

MR. GAGE: Objection.

A I see what's written here. And I -- I know what ultimate outcome was of their decision process.

Q You don't have an explanation as to why they came to the conclusion in the DDSA, days before launch, that there was no predicate device to the Prolift. Correct?

MR. GAGE: Objection.

BY MR. MAZIE:

Q You don't know why.

A Well, I can't determine from this.

Q And you think it could be a mistake?

A It could very well be.

Q Do you have any other explanations, besides a mistake?

A You know, you kind of have to be in the

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discussion to see how things went and what the basis for statements were sometimes to understand the context.

Q In all of the information, all of the depositions and the mounds of documents you reviewed, you never saw an explanation anywhere as to why in the DDSA in two places the regulatory group at Ethicon came to the conclusion that there was no predicate device to Prolift. Right?

MR. GAGE: Objection.

A Well -- well, what's the Ethicon regulatory group? The ultimate decision is Catherine Beath's. She's testified they went through the process, they followed the procedure, they made the decision, and they marketed the product.

It doesn't seem to -- to mesh with this, so to speak, sorry to use the word. But, you know, I see that testimony.

Q This document, this DDSA, which is a final document from Catherine Beath's group, doesn't make sense, does it?

MR. GAGE: Objection.

A It doesn't coincide with the final decision.

Q It contradicts it. Correct?

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MR. GAGE: Objection.

A Well, I'd have to understand the context of this thing, whether it really does or not. You know, it's a statement here. I don't know, it deserves further exploration, I suppose, with the person who wrote it. Have you deposed that person? I don't know.

MR. MAZIE: I want to mark these. Here's one, and here's another.

(Ulatowski Exhibits 20 and 21 marked for identification, to be attached to the transcript.)

BY MR. MAZIE:

Q Let me show you what's been marked as Ulatowski 20.

Have you seen this before?

A Sure.

Q This is a part of the Code of Federal Regulations, Title 21. Correct?

A Yes.

Q And this talks to when premarket notification submission is required. Correct?

A Yes.

Q And it says that a 510-K is required if a change or modification in the device that could significantly affect the safety or effectiveness of

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the design exists. Correct?
A Well, it says --
MR. GAGE: Objection.
A It doesn't quite say that.
Q What does it say? How am I incorrect?
A Are you looking at 3 I?
Q Yeah.
A The change of modification that could significantly affect the safety or effectiveness of the device. You said design.
Q Okay.
A Significant change and modification in design, material, chemical composition, so on and so forth.
Q Fair to say that if the Prolift represented a change or modification from that of Gynemesh PS that could significantly affect the safety or effectiveness of the Prolift procedure or device, that would require a 510-K, according to law?
MR. GAGE: Objection.
A Well, the setup is, the -- under 3, the device is in commercial distribution, but is about to be significantly changed or modified. Okay.
So that's the -- that's the Gynemesh device. That's the predicate is going to be changed

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or modified.
Q Okay.
A Okay? In -- in design, whatever, as stated here, energy source, chemical composition. And then that's assessed to determine whether it's significant.
Q Okay.
A The changes are significant.
Q So if --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q According to Ethicon, the Prolift procedure and system is based on the Gynemesh. Correct?
MR. GAGE: Objection.
A Well, I -- I guess one thing to point out is that FDA doesn't regulate procedures, per se; it regulates devices.
Procedures may raise issues that have to be considered, but FDA doesn't regulate a procedure.
Q Well, here you have special instruments that are used in a special way. Correct?
A There's instruments that are used in the process of implanting the Prolift device --
Q And the whole --
A -- whatever form is used.
Q And the whole Prolift procedure and system

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is Class III device. Correct?
MR. GAGE: Objection.
A The whole Prolift and procedure is Class III?
Q The Prolift system -- let's do it this way: The Prolift system is a Class III device. Correct?
MR. GAGE: Objection.
A I don't think so.
Q You don't think that the Prolift system is a Class III device?
A I don't think so. Let me just -- you know, I should have this in my brain, but I don't think so.
I don't think so. No. Part of the panel review there was a consideration whether to up classify, but I don't think it was classified substantially as a Class III device.
Q What do you think that the Prolift is? What's the proper classification of it? Or don't you have an opinion?
A Well, unless I'm mistaken, I think it's Class II.
Q Based on what? What makes it Class II? Or, I mean, I'm asking -- let me ask you this: Do you have an opinion as to what the appropriate classification is for the Prolift system?

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A As found ultimately by FDA of the 510-K review is found equivalent to Gynemesh, Apogee, Perigee ultimately, and then the new device, the Prolift, has -- then has the same classification as the predicate devices.
And in the regulations under 21 CFR, Code of Federal Regulations, the type of device is -- is specified and the classification of that type of device. I don't think it's Class III. If it were Class III, a 510-K would not be appropriate.
Q Is that your testimony?
A That's a fact.
Q Is that your opinion, that it -- if a -- something is a Class III device, a 510-K is not appropriate?
A Unless it's a so-called preamendment to Class III device, and that's not the case here.
Q So what classes require a 510-K?
A Class I, Class II, and the preamendments Class III device under special circumstances.
Q The -- if the -- if there's a major change --
A Class I. Excuse me, Class I nonexempt device, a Class II nonexempt device, and a preamendments Class III.

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Q If the Prolift constitutes a major change or modification in the intended use of Gynemesh, that would require Ethicon to submit a 510-K for clearance prior to selling the product legally. Correct?
A If in evaluating the indications for use, primarily looking at the proposed labeling, if there's -- you examine the labeling, see if there's any differences, and you assess those differences to see if there is any change that amounts to a change in intended use.
Let me just add a caveat that change in intended use was a very rare finding in a 510-K process.
Q Okay. Can you answer my question?
MR. MAZIE: I'll move to strike that as nonresponsive.
A Yeah. Okay.
Q If it was determined --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q If Prolift constituted a major change or modification in the intended use of Gynemesh, that would require or have required Ethicon to have submitted a 510-K for clearance prior to legally selling Prolift. Correct?

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MR. GAGE: Objection.
A If in the manufacturer's assessment of the Prolift labeling compared to the Gynemesh labeling the manufacturer -- or any -- just any, generically, if you look at the new device compared to the predicate device, if the manufacturer concludes that the new device has a new intended use, you need to submit.
Q And that's a matter of law. Correct?
MR. GAGE: Objection.
A Well, it's probably -- let me see what you put in front of me here.
Q Second page.
A Yeah, that -- yeah, I knew it was here. Yeah.
Q Prior to Prolift, was Gynemesh ever used in a transvaginal approach?
A Say that again, please.
Q Prior to Prolift, was Gynemesh ever used in a transvaginal approach, or method?
Let me do it this way: Prior to Prolift, was Gynemesh ever used transvaginally?
A I believe that was the case.
Q Was?
A I believe it was the case.
Q Who used -- who used the Gynemesh

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transvaginally before the advent of Prolift?
A Well, I think -- are you talking about labeling or are you talking about how physicians might have used the product from time to time?
Q Not from time to time. Was it a regular -- was it a regular and accepted use of Gynemesh to use it transvaginally prior to the advent of Prolift?
MR. GAGE: Objection.
A Was it accepted, was it regular? I don't -- those are -- I probably need to -- I think there's testimony to the effect that, you know, this occurred.
Q Well, I understand there's outliers. I want you to put outliers aside. Experimental, outliers, things like that.
Did -- let me ask it this way: Did Ethicon ever promote or list as acceptable the use of Gynemesh transvaginally prior to the selling the Prolift?
MR. GAGE: Objection.
A Promote? I don't think I received any and all advertising or promotional material regarding Gynemesh, and so I can't say with certainty. As far as did they have it in the labeling? I would have to look at the Gynemesh labeling again. If it's not there, it's not there.

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Q Have you looked at it? Let me know. Do you have your report there?
A I don't have the labeling embedded in my report.
Q All right. Let's assume that nowhere in the Gynemesh labeling or brochure or IFU or any other advertising or promotional materials it says that Gynemesh can be used transvaginally. If that's the case -- I want you to assume that. If that's the case, then the Prolift system would be a major modification in the intended use of Gynemesh.
Correct?
MR. GAGE: Objection.
A Well, probably extends the area of my expertise in regard to that finding. I know physicians did cut the Gynemesh to form it, did use it off label, if you will, if that was the case, transvaginally. The TVM studies were underway using Gynemesh.
There was that -- that basis for information that formed the opinions of Ethicon regarding supporting the marketing of Prolift.
Q Now can you answer my question.
MR. MAZIE: I move to strike that as nonresponsive.

BY MR. MAZIE:
Q I'm not asking you about outliers. I'm asking you --
A Well --
Q -- based on the promotional materials, the IFU, and the intended use of Gynemesh as sold by Ethicon, okay? I want you to assume that Ethicon never promoted or sold or told anyone in their materials that Gynemesh was appropriate for transvaginal use. If you can assume that to be the case, you agree with me that the Prolift system, as compared to Gynemesh, constituted a major change or modification in the intended use of Gynemesh.
Correct?
MR. GAGE: Objection.
A No, that's not a change in intended use.
Q It's not. Why not?
A Intended use is -- is a broad application of a term. Intended use -- is it used in urogynecological surgery? Yes. Same intended use. That's -- FDA interprets intended use rather broadly in many cases.
I would -- I would have to see what the gynecology group at FDA would consider. But I know I've applied that -- that definition very broadly in

determining substantial equivalence or the need to submit a 510-K.
Q As you sit here today you don't have an opinion as to whether or not the Prolift, as compared to the Gynemesh PS predicate device, constitutes a major change or modification in the intended use of Gynemesh. Correct? You haven't rendered that opinion?
A I didn't render that opinion. I think it probably wouldn't be considered -- I don't think FDA considered that when they contacted Ethicon about the need to submit the ADVA (phonetic) file or in talking about the 510-K process, they -- they didn't use the term "intended use changes." That wasn't their core concern.
Q I'm asking you whether you have such an opinion. You've said no. Correct?
A I just gave you an opinion. You asked me, I answered, and now you're --
Q Well, no. The first part of it was I don't have an opinion. And then you went on, I don't think the FDA looked at it.
I'm asking you whether you have an opinion, as you sit here today, as to whether or not Gynemesh, as compared to the Prolift -- I'm sorry. As to

whether Prolift, as compared to the Gynemesh PS system, constitutes a major change or modification in the intended use of the device.
MR. GAGE: Objection.
A That opinion is not in my report as one of my opinions, if that's what your question is.
Q Right.
A Can I give you an opinion at this point in time and -- as evidenced by criteria? And I can.
Q Are you rendering an opinion in this case? We'll get into that. But we'll have to --
A Well, based upon my years of experience at FDA, intended use would not be the limiting factor for this device.
Q Okay. You haven't reviewed and you don't have before you the Gynemesh documents. Correct?
A Not in front of me, but I did review the Gynemesh documents.
Q Okay. And you understand that nowhere in the Gynemesh documents, promotional materials, the brochure, the IFU, none of that, does it say that it can and should be used transvaginally. Correct?
MR. GAGE: Objection.
A I'd have to see the document. I'll just take your statement on its face.

Q Okay. Prolift, on the other hand, is intended to be used transvaginally. Correct?
A Yes.
Q Okay. Do you have an opinion as to whether or not that transvaginal use, the Prolift system, and all the tools and the procedure itself, constitutes a major change or modification in the intended use of Gynemesh?
MR. GAGE: Objection.
A It's very similar to your last question.
And, you know, again I'll answer it this way, that intended use is -- is considered very broadly. Such that it can be -- and you're asking my opinion -- it can be considered are you implanting a mesh in the -- in the pelvic space? Answer is yes. You're in the same ballpark, you're in the same intended use ballpark.
Intended use was -- again, was rarely used by FDA as a -- as a foundation for nonsignificant -- not substantial equivalence.
Q And sometimes it was used. Correct?
A Rarely.
Q FDA by law was required, by law, to require a 510-K where there's a major change or modification in the intended use of the predicate device. Correct?

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MR. GAGE: Objection.
A The regulation says if there's a new intended use, you need -- that's a significant change.
Q You haven't rendered an opinion in this case that -- as to whether or not there is a major change or modification in the intended use of Gynemesh as per the Prolift system. Correct?
MR. GAGE: Objection.
A Well, I said in my report I don't have a specific opinion regarding that. Then you asked for my opinion and I give you my opinion. So I don't -- which way do you want it?
Q Are you rendering an opinion in this case -- because then we'll get into the medicine again. Are you rendering an opinion in this case as to whether or not Prolift as compared to Gynemesh constitutes a major change or modification in the intended use of Gynemesh?
MR. GAGE: Objection.
A I didn't spell it out in that -- those specifics. I think my Opinion 1, though, covers a lot of ground. Intended use is part of that process of evaluation. Ethicon followed that process. They determined there was not a new intended use. They determined that there were no significant changes.

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And they made a decision to market. So that topic was -- was considered by Ethicon.
Q Okay. You went again back to process. You're not familiar with the -- the actual science and the urogynecologic issues, as we've already discussed numerous times. Correct?
MR. GAGE: Objection.
A I'm not a urogynecologist, but I reflect upon FDA's opinions in rendering a substantial equivalence decision. They sped right past I think the intended use aspect.
Q I'm asking you as to your opinion. I'm not talking about FDA. I'm asking you, after evaluating all the medical information, all the documents, do you have an opinion outside of process, the process that was used, as to whether or not Prolift as a system represents a major change or modification in the intended use of Gynemesh?
MR. GAGE: Objection.
BY MR. MAZIE:
Q And if you do, then we'll get to the science.
MR. GAGE: Objection.
A I didn't render an opinion specifically on intended use, in my opinions.

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Q Okay. And you're not rendering an opinion, otherwise we'll get into the science. I need to know that.
A Well, but then you say "and you're not rendering an opinion." Well, I'm -- and then I provide you a response.
I -- it's not in my report.
Q Okay. And you're not rendering nor intending to render such an opinion. Correct?
A If it's not in my report.
Q Fine. Then we can move on.
I want you to look at the next one.
MR. MAZIE: Is it 21?
Why don't we switch out.
VIDEO SPECIALIST: The time now is 4:30. We are going off the record. This is the end of Disk Number 4.
(Short recess.)
MR. MAZIE: You know we want a rough.
VIDEO SPECIALIST: The time now is 4:45. We are back on the record. This is the beginning of Disk Number 5.
BY MR. MAZIE:
Q Mr. Ulatowski, I'm going to show you what's been marked as Ulatowski 21. Is this the guidance for

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when to submit a 510-K that's been in effect since 1997?
A When to submit a 510-K when there's a change to an existing device, yes.
Q Okay. And this was the -- the current guidance during the time that the Prolift was being considered and sold. Correct?
A Yes.
Q Okay. And let's go to Page 28, which is the main flowchart.
You cite to this flowchart and this document in your report. Correct?
A I cite to the document, and I cite to Ethicon's use of -- well, at least the relevant flowcharts that they filled out.
Q Does this flowchart --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Was this -- should --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Should this flowchart have been used by Ethicon in determining whether or not to submit a 510-K for the Prolift?
A Well, this is the main flowchart, so this

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is kind of the beginning of it.
Q Well, let me ask it. Which -- there's that flowchart, there's a flowchart next to it, then there's a flowchart next to that. So there's the main flowchart, Flowchart A?
A Right.
Q Flowchart B.
A Right.
Q Okay? And I don't think the other ones apply.
Which of these flowcharts applied and should have been used by Ethicon in determining whether to submit a 510-K for Prolift?
A Well, if I can turn to my report, hopefully I can identify the flowcharts they used, which I'd like to do.
Q Okay. While you're doing --
A For starters.
Q While you're doing that, can I ask you a question? Can you multitask?
A At this time of day, I don't know. But go ahead.
Q Okay. I'll wait.
My question is this. Why don't you think on it while you're looking. My question is this: Are

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these flowcharts that Ethicon used, or are those flowcharts that Ethicon should have used?
A And that's the reason I want to --
Q You're trying to find out.
A Yeah.
Q Okay.
A Yeah.
But I didn't embed the flowcharts in my report, so I'd have to go back to the source documents.
Q Okay. Which you don't have with you?
A Which I don't -- it was in those -- a Project D'Art document.
Q Which particular document are you referring to?
A I have the Bates numbers.
Q Why don't we do this: Tomorrow can you bring that Project D'Art document you've been referring to? I'm sure I have it here somewhere, but I --
A Yeah, I can. It's a -- it's a small volume thing.
Q Can you bring that?
A Sure.
Q And you're also tomorrow, just so we're

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clear, you're going to be bringing all the other expert reports and depositions we discussed, to the extent you can find them at your home or office.
A I'm going to bring them to him and have a discussion.
Q Right. I understand. Okay.
MR. GAGE: "Him" being William Gage, for the record.
THE WITNESS: Yeah.
A Just for clarity, am I supposed to bring the full report or just titles of a report or -- you know, I mean, I can bring my PC that hopefully has all the reports on it.
MR. GAGE: Let's -- let's remember to talk about that as soon as we finish here.
THE WITNESS: Okay.
BY MR. MAZIE:
Q So going back to it, do you have an opinion as you sit here today as to whether these flowcharts should have been -- which flowcharts should have been used by Ethicon during their regulatory process in determining whether to submit a 510-K for the Prolift?
A What I'd like to do is refer to what they did for starters.
Q Okay.

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A And then I'll reflect upon --
Q Okay.
A -- what's here.
Because they did follow -- well, they did use A and B, I think.
Q Can you do that today?
A Well, I can -- I can identify them from my report, I think. I think I did see it. I think it was A and B they used.
I think it was A and B they used, according to my report.
Q So Ethicon used Flowchart A and Flowchart B in its determination of whether or not to submit a 510-K for the Prolift?
A That's what I have in my report.
Q Okay. Was it appropriate for Ethicon to use Flowchart A or B -- I'm sorry, Flowchart A and B in determining whether to submit a 510-K for Prolift?
A I think so.
Q Okay.
A Yes.
Q If we look at Flowchart A, it says, "Does the change affect the indications for use."
Do you see that?
A Yes.

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Q And what this is -- correct me if I'm wrong. This says if -- does the change between the predicate device and the current device affect the IFU. Is that correct? Is that what that's asking?
A Yes. Yes.
Q Okay. And if there is a change in the IFU for the Prolift as compared to the -- to Gynemesh, that would require, according to this flowchart, a 510-K submission before marketing the Prolift.
Correct?
A Well, it says does the change affect the indications for use. And -- and that's -- that's further explained in the document, and in other FDA guidance, as a matter of fact.
Q What does that mean?
A Well, I'm just saying that this is a flowchart. The document itself goes into greater detail, explaining each of the decision points. So a little more detail.
Q Let's go to Page 24.
A And there's another FDA document that actually goes into changes in indications for use and whether they affect the indications.
Q Let's go to Page 24.
A Okay.

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Q Keep your finger on the flowchart.
A I've got it.
Q Okay. On Page 24 at the bottom it says Indications For Use, and then it discusses what constitutes indications for use.
A Uh-huh.
Q And the changes.
A Yes.
Q Correct?
A Yes.
Q And it says that the indications -- "The indications include all the label patient uses for the device, and for example," and it gives some examples.
Correct?
A Yes.
Q And it says, "Part of the body or type of tissue applied to or interacted with."
Do you see that?
A Yes.
Q Okay. And Gynemesh, as sold and promoted by Ethicon, was not for use transvaginally in the pelvic area, was it?
MR. GAGE: Objection.
A Well, we discussed this before. I -- I probably want to look at the Gynemesh labeling again,

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PS labeling again. It's whether you interpret this broadly or narrowly, which FDA will do. Is this used in -- is the mesh applied, for example -- as an example, is the mesh applied in -- in pelvic organ surgery, in the pelvic tissues. It can be generally applied. That's how FDA considers products, case by case, broadly or narrowly.
Q Do you medically know -- do you know where --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Do you know how Gynemesh was primarily intended for use, what part of the body?
A Well, there was a -- a pelvic floor -- pelvic surgery indication. In fact, I think I have it in my report, the exact indication.
Q Okay. How much --
A If I can refer to it.
Q Sure.
A I think it was -- that was very important. It was a change. Let me see here what I've got.
I have Gynemesh on Page 38 of my report, "tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor and vaginal wall prolapse where surgical treatment is intended

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either as mechanical support or bridging material for the fascial defect."
And I have in my report indicated that the Prolift was essentially the same indication.
Q Okay. And if we look at the -- go back to Flowchart A.
A Took my finger off. Okay.
Q It's on Page 29.
A Okay.
Q Do you know if indications for use relate to the procedure?
A I -- the reason I pause is, I -- I think FDA didn't consider the procedure so much in this part.
Q I'm asking you; I'm not asking about FDA.
I'm asking you, is the Prolift procedure considered -- you may not have an opinion. I'm asking you whether you have an opinion as to whether or not the Prolift procedure constitutes a change affecting the indications for use of Gynemesh.
MR. GAGE: Objection.
BY MR. MAZIE:
Q As per this flowchart.
MR. GAGE: Objection.
A The reason I refer to FDA is because those

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are the folks in that particular branch who would assess the particular changes, the labeling, the procedure. The FDA folks did believe that the procedure and the change in the shapes may raise issues. But that -- that's not on -- that's not on this part of the flowchart.

Q Where is it? Where does that appear?

A In the document here, in discussion of clinical aspects, new issues and clinical aspects.

Q Which flowchart does that apply to?

A Let me just take you down here to this one. Bear with me here.

Oops. Excuse me. Well, that -- that part's actually if we look at Flowchart B, B8.3, that's what I was talking about. So not A, but B.

Q BA.33?

A B8.3, in Flowchart B.

Q Oh, okay. "Do results of design validation raise new issues of safety and effectiveness."

Is that what you're referring to?

A Yeah. And if you look at the explanation of B8.3 in the document, which I didn't keep my finger on, Issues of safety and effectiveness. Question safety effectiveness may be associated with the design change.

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Q What --

A There's another part, too, as well. Some relevance to B8.2. So in any case, we're kind of resident in B more than A.

Q Okay. And do you agree that if --

A But that's, you know -- I would look at Ethicon, how they filled this out, to see the path that they reached. They went through the process and made some determinations here.

Q Do you agree that if the results of design validation process raise new issues of safety and effectiveness, that a 510-K would be required before selling Prolift?

A I've -- I've talked to people about this. Maybe a little bit long answer, but let me explain, and you'll understand.

In -- in a regulation, 510-K regulation says, is there a significant change. And so you go through the document. And then in the 510-K review process, there's a determination whether there are new issues, new types of issues related to the changes. And if there are, you're not equivalent.

So it's -- when this document was created, you know, I actually raised the issue along the way at FDA, but the essence of the decision in this document

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is, is there a significant change. The essence -- one of the parts of the 510-K review is, are there new issues.

In fact, the 510-K reviewer said, Well, we think you've got a significant change, and you may have new issues, and we're going to explore those new issues, potential new issues, and see if there are new issues, and render a decision. And then they finally decided there were no new issues.

So I'd rather that -- for clarity's sake, I would rather this document say, are there significant issues, are there significant things, you know, to kind of tie it to the regulation.

Q Is it fair to say if there are new significant issues regarding safety and effectiveness for the Prolift as compared to Gynemesh, a 510-K is required before Prolift can be sold legally?

A If there's --

MR. GAGE: Objection.

A If there's significant -- I'll just use the term. If there's significant issues according to the flowchart, decision flowchart, you come out, in terms of Flowchart B, just to turn to it, you end up at need 510-K.

If -- if you've -- you end up new issues in

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a 510-K review, new types of issues, you end up on the 510-K decision tree as not substantially equivalent. So it's kind of catch-22. Do you see where I'm getting?

So that's why, if there's new issues. So are there significant issue -- significant factors going on here? Yes, 510-K. By the company's estimation, evaluation.

And then FDA -- if there is, then the FDA evaluates the new issue, new types of issues, whether there are any.

Q All right. So just so I understand you and the jury understands you, if there are or were new significant issues when comparing Prolift to Gynemesh, if that were the case, that would have required a 510-K, as per FDA guidance. Correct?

A If Ethicon went through the flowchart, came up with new 510-K, it would be self-evident.

Q Okay. And going through this Flowchart B, which is the one you say applies. Right?

A Well, they looked at A and B.

Q Okay. But you --

A I don't recall exactly the path they took on A, but.

Q You think Flowchart B is the one that --

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that really applies here.
A Well, they used Flowchart A and B, and you asked me a question about one thing or another, and I took you to B. It doesn't mean A is irrelevant.
Q Okay. If the change from Prolift to Gynemesh affected the indications for use, that -- that would require a new 510-K before Prolift could be sold. Correct?
A If in the company's evaluation and conclusion, as documented, they came to the conclusion, the regulatory group, Catherine Beath came to the conclusion there was a change affected indications for use, the path is clear, as far as the 510-K.
Q Okay. If Ethicon's regulatory group came to the conclusion that clinical data, clinical data was necessary to establish safety and effectiveness for purposes of substantial equivalence between Prolift and Gynemesh, that would have required a 510-K before selling Prolift. Correct?
A Well, let me preface my response by saying, I always -- in reviewing 510-Ks, I always consider that to be, I'll call it, de novo clinical experience. By that I mean in the design controls process, the design validation was a clinical study. Meaning be it

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a controlled study, uncontrolled, the case study, whatever the case was.
They had clinical information in the 510-K, but it wasn't of the type envisioned here in this flowchart, as far as the decision tree is concerned.
Q Now can you answer my question? My question is, if Ethicon's regulatory department came to the conclusion that clinical data was necessary to establish safety and effectiveness for purposes of substantial equivalence between Prolift and Gynemesh, a 510-K would have been required before legally selling Prolift. Correct?
MR. GAGE: Objection.
A Well, I don't think -- as I recall, that clinical -- the need for clinical data, per se, is -- is evidence of -- takes you to a 510-K in all instances.
I think the document itself states that it may be the case, it may frequently be the case that if you need clinical data -- I forget the words they used. That may be the case. But it leaves the door open on whether it's always the case.
Q So you don't have an opinion one way or the other whether or not if clinical data is necessary to establish safety and effectiveness for the purpose of

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substantial equivalence, whether or not that would require in all instances a new 510-K.
A It wouldn't.
Q Okay. And in this instance, if Ethicon came to the conclusion that clinical data was necessary to establish safety and effectiveness for purposes of substantial equivalence between Prolift and Gynemesh, would that have required a 510-K, if they came to that conclusion?
A If they came to the -- well, not necessarily. If they came to the conclusion that in our design and review process -- again, I explained this, I guess. In the design and review process we need a clinical study for validation of this product, that -- that probably would have been a strong consideration for a 510-K.
But what they did is they relied upon clinical information already underway. They leveraged information, which companies will do. They'll take whatever information is out there and determine whether it's relevant, and to use it as a basis for -- for their product.
Q Let me ask you, if the people at Ethicon, the results -- they saw that the results of the design validation raised new issues of safety and

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effectiveness between Prolift as compared to Gynemesh, that would have required them to submit a new 510-K before legally selling Prolift. Correct?
MR. GAGE: Objection.
A Well, the validations would -- would be assessed to determine, in fact, if that was the case. If that was a finding, if that was a statement, it would probably be subject to further review, whether from a regulatory point of view, looking at this document, whether it would require a 510-K.
Q So you can't tell us whether that would require a 510-K or not?
A It would require further assessment. So it wouldn't necessarily require a 510-K.
Q But it would lean towards having a 510-K?
A It would be something that would have to be considered.
Q Strongly considered, because that's what the flowchart says. Correct?
MR. GAGE: Objection.
A I haven't memorized this thing, even though I used it for years and years. Let me see.
Well, yeah, it has to be considered, other -- you know, if the answer is yes, then it takes you to 510-K. That's what the flowchart tells you.

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Q Right. So just so we're clear, if Ethicon determined that the results of the design validation raised new issues of safety and effectiveness as between Prolift as compared to Gynemesh, that would have required them to strongly consider a -- filing a new 510-K. Correct?

MR. GAGE: Objection.

A Yeah. It -- you know, as I said, my belief about new issues, because that's kind of a catch-22. Does it raise significant aspects that have to be assessed, and whether they're so significant that it requires a 510-K.

Q If the issues are significant for safety and effectiveness when you look at Prolift versus Gynemesh, according to this decision tree, and all guidance, that would require a 510-K before Prolift could be legally sold. Correct?

MR. GAGE: Objection.

A If that was the final determination by Ethicon, its regulatory staff and its decision process as documented, that would be the process. It -- the flowchart's clear on that fact.

Q 510-K?

A If that's the finding, according to the flowchart.

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Q Okay. All right. Put that away.

You say that in your experience FDA does not enforce advertising claims?

A Advertising is -- what FDA concentrates on is -- is other forms of misbranding. Because advertising, direct-to-consumer advertising is only for certain devices, for starters. It's limited to restricted devices, and -- and Gynemesh isn't a restricted device.

If the advertising relates to a new claim, new intended use that might have implications for a 510-K, yes, perhaps. If the advertising has implications for whether potentially the product requires a 510-K itself, that's being advertised, yes. And those -- those considerations occur.

It's -- it's not -- FDA's advertising staff is -- has been gearing up to do other things. I see they -- they just reorganized. So I'm not sure what they're going to be doing now. But what we did is we focused in on products, based on advertising, products that may have required a 510-K or a PMA that were advertised.

Q If there was a misstatement in the patient brochure, that would be within the jurisdiction of FDA to enforce. Correct?

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A Well, that would be considered by FDA, if it was brought to our attention, if it was significant. There's a lot of assessment there that would have to take place.

Q If there was a significant misstatement --

MR. MAZIE: Or strike that.

BY MR. MAZIE:

Q If there was a material misstatement or omission in the patient brochure, that's something that FDA would look at and, if appropriate, enforce. Correct?

MR. GAGE: Objection.

BY MR. MAZIE:

Q Or take action?

A May look at. It depends whether it would be brought to our attention.

You know, looking at the evidence, understanding the context, probably doing an inspection, talking with the company, and then taking that all into account, talking with the experts and deciding whether it was material, whether it was important. And then moving forward, if necessary.

Q You said, though -- and I want to get back to it -- FDA does not enforce advertising claims. That's not always the case. Right?

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A Typically FDA, as I said, in terms of claims, in terms of advertising, we look primarily at whether this product was legally marketed or not.

The claims, you know all claims mostly came to FDA's attention is through manufacturers' complaints. One manufacturer against another, saying, Well, this manufacturer is saying this or that. You know, the marketing kind of angle. And quite often we didn't want to get into tit for tat between two companies.

Q FDA itself doesn't consider patient brochures advertising, does it?

A No.

Q And if FDA -- FDA wanted to enforce against advertising claims, it could; it's within its regulatory jurisdiction. Correct?

MR. GAGE: Objection.

A Yes, I think we'd make an effort, if necessary, to try and proceed with an action, if necessary and warranted, based on the evidence.

Q Okay. It's a case-by-case basis. Correct?

A Case by case.

Q Okay.

A I don't recall ever taking an action against a patient brochure.

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MR. MAZIE: Objection. Move to strike from "I don't recall" on.
BY MR. MAZIE:
Q Did you read testimony that Ethicon regulatory affairs relied on medical affairs to identify each of the risks of Prolift?
MR. GAGE: Objection.
A Can you please say that again.
Q Sure. Is it your understanding that Ethicon regulatory affairs relied on medical affairs at Ethicon, as well as its outside consultants, to identify each of the risks of Prolift?
A Well, I know that they -- that they did rely on medical affairs in regard to medical issues.
Q Okay. And that's appropriate, to do that?
A I would say so.
Q Okay. Let me show you this.
MR. MAZIE: We'll mark this.
(Ulatowski Exhibit 22 marked for identification, to be attached to the transcript.)
MR. GAGE: Do you have an extra copy?
MR. MAZIE: Yeah. Hold on a second.
Here you go.
BY MR. MAZIE:
Q This is a portion of the testimony of Sean

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O'Bryan. You know who he is, in regulatory affairs.
Correct?
A Yes.
Q Okay. Look at Page 107, Lines 3 to 13. Tell me if you have seen this before.
"QUESTION: And to the extent you had input into the Prolift IFU drafting process, you certainly wanted to make sure that any warnings of any significant potential risks would be explicitly communicated to the intended or foreseeable users of the Prolift. Correct?
"ANSWER: Sure. I rely on the medical team to tell me what is significant and what is important to convey into the instructions for use, package insert."
Have you seen that before?
A I read the deposition. I see that, yes.
Q And from your perspective, that's what regulatory -- regulatory affairs did at Ethicon; they relied on the medical team, meaning medical affairs and outside medical consultants, in determining what were the risks of the use of Prolift. Correct?
A Well, I think that they're talking directly about the IFU here, what's stated in the IFU --
Q Okay.

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A -- in regard to those factors.
Q And the IFU has to list all the risks and contraindications, does it not?
MR. GAGE: Objection.
A It has to list warnings, precautions, contraindications, adverse effects.
Q Okay.
A And I opined on that.
Q Okay. And we'll get to that tomorrow, but we'll get to that.
But -- so from the perspective of listing all of the warnings and contraindications and adverse events for the Prolift, regulatory affairs at Ethicon relied on their medical team, meaning medical affairs and outside medical consultants. Correct?
A Well, he just refers to the medical team in this deposition here, page.
Q Okay. Do you know who the medical team was?
A Well, that was probably Robinson and his -- his staff.
Q Okay. Medical affairs?
A Medical affairs.
Q And did you read Robinson's deposition where he testified that he had outside people that

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also he relied on?
MR. GAGE: Objection.
A I'd have to review that again, but I'll take it on face what you said.
Q Okay. So just so we're clear, I'm just trying to -- there's no tricks here.
Sean O'Bryan testified then when they were evaluating and considering all of the adverse events, the contraindications, and the potential risks of undergoing a Prolift procedure, that they relied on their medical team. Correct?
A Yes, that was a key input.
Q And that's appropriate to do that, correct, for regulatory affairs, because they're not usually physicians or have the type of specialized medical training, to rely on their medical affairs people and other medical individuals -- medical consultants. Correct?
MR. GAGE: Objection.
A They rely on them. The regulatory staff may edit or tweak, have conversations to clarify labeling, things like that.
Q But as to the science, it's appropriate to rely on medical specialists. Correct?
A Yes.

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Q Okay. All right. Put that away.
A Medical specialists on staff.
Q On staff or, as appropriate, outside of staff, as special consultants. Correct?
A Whatever they call upon specifically to provide opinions.
Q Okay. Do you agree that the instruments, the special instruments that were created for Prolift, are considered components or accessories to the Prolift system?
A Well, they're part of the kit, a kit. I -- I didn't opine on that aspect.
Q Okay. If you have no opinion, you let me know that.
A I didn't express any opinion in my report.
Q All right. And you have no opinion that you're rendering in this case as to whether or not the instruments that are part of the Prolift system are components or accessories to the Prolift system.
A I don't think I rendered an opinion. If I'm in error, then I -- I don't recall. I reflected on, in the Project D'Art how they approached the instruments. That's the extent of it.
Q If you -- if tonight when you go home and you look at your report, and you're in error and you

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think you did render an opinion on that, you'll let us know tomorrow. Otherwise I'll assume you have no such opinion. Okay? Is that fair?
A I understand.
Q Okay.
MR. GAGE: If you choose to terminate before 6:00 p.m., I will not argue or state or imply to any court that you had available time this evening and you wasted it.
MR. MAZIE: Well, what time are you going to give me until tomorrow?
MR. GAGE: I've -- let me check, see what time my flight leaves.
MR. MAZIE: It's all about Bill.
MR. GAGE: It's about you. I want you to get home and see your family, you know. Because you've been traveling a lot.
MR. MAZIE: Yeah, I travel none. First time in a year I've traveled, except on vacation, which I do quite often.
(Discussion off the record.)
MR. GAGE: My flight leaves at 7:55 out of -- so I think 6:00 is just my absolute cutoff.
MR. MAZIE: That's fine. And I'm hoping to be done because I have a 4-something train which I

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don't know what's going to happen.
MR. GAGE: But I mean that seriously. I'm not going to -- if you want to --
MR. MAZIE: I just picked that.
MR. GAGE: I mean, I know it's late, and you've been going and going. I mean it seriously. If you want to terminate tonight, I'm not going to come back tomorrow and say --
MR. MAZIE: Well, you said you're giving me until 6.
MR. GAGE: I'm giving you until 6. But I'm not going to raise that and say, On Thursday evening you had an additional 30 minutes and you chose not to take it. I'm not going to do that.
MR. MAZIE: I appreciate it. But I want to finish him tomorrow, and that's the most important thing. So let me just -- give me a second to figure this out.
BY MR. MAZIE:
Q Let me ask you this: I think we're all in agreement on this. Initially Ethicon never -- did not --
MR. MAZIE: Strike that.
BY MR. MAZIE:
Q Initially Ethicon did not submit a 510-K.

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Correct?
MR. GAGE: Objection.
A For Prolift.
Q Correct. For Prolift.
A In 2005, yes, they did not.
Q And it sold Prolift for a number of years before it was notified by the FDA that it needed to have a 510-K for Prolift. Correct?
A Well, how it unfolded is after a couple of years, upon submission of Prolift +M, FDA made a recommendation which Ethicon voluntarily responded to.
Q And Ethicon came back, and it did ultimately submit a 510-K. Correct?
A There was transformation of information to a 510-K. There was information -- yes. Yeah. Ultimately it was absorbed into the Prolift +M 510-K.
Q And Ethicon told, Ethicon told the FDA that Gynemesh was no longer the predicate device; it was now the Apogee and the Perigee systems. Correct?
MR. GAGE: Objection.
A No, Gynemesh was still in there, but they added Apogee and Perigee --
Q Okay.
A -- for Prolift.
Q Okay.

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A They added UltraPro. They had UltraPro +M, also.
Q Have you ever evaluated whether or not Apogee and Perigee are appropriate predicate devices for Prolift, or is that beyond your opinion?
A I don't have an expressed opinion specific to Apogee and Perigee in one of my opinions.
I did review the Perigee 510-K to see -- I, first of all, identified Apogee and Perigee as predicates identified by Ethicon. And then I looked at the -- and then I looked at the Perigee 510-K to see what that was all about. I looked at the 510-K review process to see what FDA thought about those predicates. It all seemed to be appropriate, if that's your question.
Q Are you rendering an opinion in this case as to whether or not Apogee and Perigee are appropriate predicate devices for Prolift?
A I don't have a -- well, let me see. Let me see if it's embodied in an opinion here.
I don't have a specific opinion regarding the appropriateness of using Apogee and Perigee. In my report I note those were predicates, in part of the submission process.
Q Right. So you have no opinion as you sit

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here today, nor are you offering one, as to whether or not Apogee and Perigee were appropriate predicate devices for Prolift. Correct?
A There's no opinion in my report specifically.
Q And you're not rendering any such opinion?
A It's my understanding I cannot add one now, then the answer is no.
Q And are you aware of the fact that Dr. Arnaud testified under oath that Apogee and Perigee were significantly different devices than Prolift?
MR. GAGE: Objection.
A If that's a deposition that I haven't read, well, I haven't read that.
Q Okay. Is that type of information that should have been provided to FDA with the 510-K, that one of the creators of the Prolift system believes that Apogee and Perigee are significantly different than Prolift?
MR. GAGE: Objection.
A Just as a general sense, after reviewing innumerable 510-Ks, what is appropriate to indicate as a -- as a predicate, companies more often than not take a very broad view.

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So Arnaud thinking one way is interesting. The regulatory people have a different mindset, see the world a little differently in terms of -- of the regulatory process, and provided them as predicates. And FDA didn't -- I guess didn't blink an eye when they saw it.
Q Well, you don't know what FDA looked at specifically internally?
A I don't see a comment, I think, related to that. So I'll have to review again what they said about Apogee and Perigee. But I don't recollect any big brouhaha about Ethicon listing Apogee and Perigee.
Q As you sit here today, do you know specifically who worked on the Prolift 510-K issue and Prolift +M 510-K issue at FDA?
A Well, Dr. Dang I think, was mentioned. Of course Dr. Corrado would have been in the mix, Dave Krause as the branch chief would have been in the mix. Probably others behind the scenes whose names weren't mentioned.
There was a meeting where people were identified, so those people were obviously in the mix on the FDA side.
Q Sitting here today, you don't know specifically who was involved, every single person

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that was involved in the determination of the Prolift 510-K at the FDA. Correct?
A Well, there -- there are some people identified in the record. It doesn't mean that other people weren't brought to the table or consulted on the submissions. That --
Q Well, you have no facts that you know as to specifically who was involved --
A Well, Dr. Dang, obviously.
Q -- other than the few people who were listed?
A Yes. Yes.
Q Okay. And you don't know how many man-hours each person put in on the Ethicon Prolift 510-K. Correct? At the FDA?
A No, I wouldn't know that specifically. Looking at the letters and the reviews, and 37 years of experience in writing reviews, it wasn't a trivial amount of time.
Q Okay. You don't know as you sit here today how many hours were put by anyone at the FDA specifically in reviewing the Prolift 510-K. Correct?
A Other than to say it was a -- I believe a probably considerable amount of time, based on my experience.

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Q But you don't know specifically.
A No. I wouldn't -- I would have no knowledge of their timecards.
Q And you've never spoken to anyone at FDA concerning their interaction with Ethicon or review of the 510-K involving Prolift. Correct?
A Not to my knowledge, as I stated earlier.
Q And it would be inappropriate for you to actually, if you had knowledge, to actually testify regarding it. Correct?
MR. GAGE: Objection.
A No, I wouldn't say that would be the case.
Q Why not?
A If what I'm basing my opinions are -- are the records before me provided by counsel through discovery or whatever, I can opine all day on those things.
Q You gave an opinion that the total processing time for the Prolift 510-K was 446 days when the average is 109 days. Correct?
A Yes.
Q You don't know whether anybody just put aside the entire project for months on end, do you?
MR. GAGE: Objection.
A Well, in my experience in OD, which is

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considerable, managing 510-K reviews, looking at the letters, the thoroughness of the letters, the meetings, the -- there was a considerable amount of time.
So, again, how much time, specifically how many hours, I couldn't tell. I can tell that it's a considerable amount of time.
Q All right. Do you know whether or not it could have been done in 100 days?
A Total time of review from submission to --
Q Sure.
A -- final decision?
Q Sure. If they wanted to put enough people on it.
MR. GAGE: Objection.
A Well, that means that the company has to respond quickly, too. The company has to provide a response in a timely way, too.
Q My point is, you don't know in the 446 days what specific days they were working on the 510-K at FDA, what days they weren't working on it, how many hours they put in, and how many people actually worked on it. Correct?
A Well, Dr. Dang, Dr. Corrado, Dr. Krause, I mean, those are people who would work on it. The

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number of hours they spent on it, I wouldn't know the specific number of hours. I know in the review process, when you pick up a 510-K, you try to stick with it until you're done with it as far as the -- the review process. You try not to divert your attention until you've completed that review.
So you can kind of -- when something was submitted, time it out to when Dr. Dang responded, submission, response. During -- when the company is doing their thing, Dr. Dang may have picked something else up to fill his time. You know, that happens, that's the way it works. But while he was working on it, submission to response, he was probably working on it.
Q But you don't know that, do you, specifically?
A Well, I do know that after 37 years of experience at FDA and how people do the 510-K reviews.
Q How long was Dr. Dang's -- how much vacation did he take during that year?
A I don't -- I wouldn't know.
Q Do you know if he was on medical leave?
A I wouldn't know that.
Q Do you know if he went to Asia for three weeks?

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A I wouldn't know that.
Q Specifically you don't know what was done on a daily basis by anyone in the 510-K review at FDA for Prolift. Correct?
A Not specifically in this instance. But as a general course of how 510-K reviews, I can -- I can provide you with probability that they were focused on it.
Q You don't know specifically; you're speculating. Isn't that correct?
A Based upon 37 years of experience, is that speculation? I don't know. You tell me.
Q Okay. Let me just see what we've got. You may be done for today, but let's just look.
MR. MAZIE: Okay. We can break here until tomorrow.
VIDEO SPECIALIST: The time now is 5:37 -- 5:38, excuse me. We are going off the record. This is the end of Disk Number 5.
MR. GAGE: David, you had asked Mr. Ulatowski about the amount of money he had earned to date, and I can't remember what he told you. But we sent some e-mails around, and it looks like his last invoice was dated 11/1/2012. And when you include that invoice, the total amount that he has

billed to the litigation that he's being deposed in today was $93,362.50.

MR. MAZIE: Okay.

(Signature having been not waived, the deposition of TIMOTHY A. ULATOWSKI, M.S., was adjourned at 5:39 p.m.)

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Debra Ann Whitehead, the officer before whom the foregoing proceedings were taken, do hereby certify that the foregoing transcript is a true and correct record of the proceedings; that said proceedings were taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 7th day of December, 2012.

My commission expires:
September 14, 2013

NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA

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ACKNOWLEDGMENT OF DEPONENT

I,____________________, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____

TIMOTHY A. ULATOWSKI, M.S. DATE

Subscribed and sworn to before me this _____ day of ______________, 20____.

My commission expires:______________

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Notary Public

LAWYER'S NOTES

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